The Psychosocial Cancer Evaluation Toolkit: developing a tailored evaluation protocol and interface for the evaluation of cancer support initiatives.

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Thesis submitted in partial fulfilment for the award of the degree of Doctor of Philosophy

University of Wales Trinity Saint David

2024

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DECLARATION

This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

Signed ..... (candidate)

Date .....19/01/2024.....

STATEMENT 1

This thesis is the result of my own investigations, except where otherwise stated. Where correction services have been used the extent and nature of the correction is clearly marked in a footnote(s). Other sources are acknowledged by footnotes giving explicit references. A bibliography is appended.

Signed ..... (candidate)

Date ..... 19/01/2024.....

STATEMENT 2

I hereby give consent for my thesis, if accepted, to be available for deposit in the University's digital repository**.**

Signed ..... (candidate)

Date ..... 19/01/2024.....

Acknowledgements

Firstly, I would like to thank the University of Wales Trinity Saint David for providing the facilities to enable me to carry out my research and develop as a researcher, and the KESS2 team who I am so grateful to have received a studentship from.

I would like to thank the team at Tenovus Cancer Care, specifically Dr Tim Banks, Jess Hall and Dr Hannah O'Mahoney for their support during the collaborative nature of this research. I was always made to feel welcome, valued and supported throughout the whole process and it was a privilege to work alongside your team.

I would like to thank the participants who made this research possible. From those affected by cancer giving their time and expertise, to my friends and colleagues who took part in pilot studies and provided invaluable feedback along the way.

I would like to thank Dr Nik Whitehead and Dr Kemi Ademoye for their supervision and guidance and for welcoming me into their Discipline. I would like to thank my colleagues, my second family, in the Psychology and Counselling team, especially to Dr Kate Williams for stepping in to supervise in my final year, Dr Paul Hutchings for providing wisdom and support throughout and to Stacey Coleman and Dr Katie Sullivan for not only their support, but their friendship over the last few years. I couldn't have done it without you all!

I would like to express my greatest thanks to my Director of Studies, my supervisor, and my mentor for the last four years (and beyond), Dr Ceri Phelps. You have instilled a standard in me that I will take forward into any future research opportunities, whereby we do this for them, the people, the ones who make the research possible and who it impacts the most. I would not be writing this if it weren't for you and your belief in me when I didn't quite believe in myself. You have pushed me to grow over the last four years and have always had my best interests in mind with every opportunity that arose.

Finally, I would like to thank my family and friends who have listened to me say 'I can't, I've got work to do' for the last four years and have listened with patience and kindness when I have explained what my research is about, always showing interest and offering support. Thank you specifically to my husband, Martin, who has supported me through all my academic ventures and struggles, for dragging me out of the house to walk the dogs and dealing with all the ups and downs that have come with my brain navigating this journey.

Thank you all.

Abstract

The psychological impact of a cancer diagnosis and the subsequent cancer journey on the individual is well recognised within the psycho-oncology literature, and within the UK alone there exists a plethora of psychosocial interventions and initiatives that seek to support those affected by cancer through a variety of mechanisms. Whilst clinical care and treatment of cancer are delivered within the UK National Health Service (NHS), a significant amount of psychosocial care is delivered through third sector organisations in the form of cancer charities, yet these suffer from a lack of robust and comparable evaluation. This thesis presents a body of applied research, funded through a KESS II studentship in partnership with Wales-based cancer charity Tenovus Cancer Care, that uniquely combines the disciplines of health psychology and applied computing to develop and evaluate an evaluation protocol and research outcome interface (T:POT) that addresses the current lack of systematic evaluation protocols available for Tenovus and other cancer charities. Firstly, a systematic literature review identified and evaluated the methodological quality of existing psychosocial patient reported outcome measures (PROMS) and led to the identification of eleven cancer-specific PROMS, many of which captured similar or overlapping constructs such as quality of life, anxiety and depression. Informed by the constructs identified in this review, empirical study one employed a modified online Delphi technique to attain expert consensus on which psychosocial health constructs were considered the most important and relevant to measure when evaluating the psychosocial impact of a cancer support service. 24 psychosocial constructs were identified that were then mapped against the PROMS to produce a core set of outcome measures which capture quality of life, unmet needs, loneliness and fear of cancer recurrence These measures formed the basis of the Tenovus: Psychosocial Outcomes Toolkit (T:POT) housed within a bespoke computer interface. Empirical study two contained a series of user-experience testing techniques including Think Aloud methodology to pilot the acceptability and usability of the T:POT interface and revealed overall that the system works well and for most elements was considered above average against the benchmark standards. The interface achieved the desired outcome, it was considered easy to use and that confidence would grow with more use. This process also allowed for design issues to be identified and then refined for the final product. The final empirical study was an evaluation of T:POT with an existing Tenovus Cancer Support Initiative and revealed the need for further development of some aspects of T:POT and the need for a larger scale evaluation and ongoing development work.

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Chapter One: General introduction

This chapter provides key background context to the overall aims and objectives of the body of work contained in this thesis. Starting by briefly explaining the nature of the funded PhD studentship supporting this research, before introducing the key background literature and context within which this research is positioned. The chapter ends with a brief overview of the methodological approach and the structure of the thesis.

The research contained within this thesis was fully funded through a Knowledge Economy Skills Scholarship (KESS2) studentship, which is an initiative supported by European Social Funds (ESF) through the Welsh Government. KESS studentships are designed to provide an opportunity for doctoral and masters level research students to collaborate with an active business or company partner which aim to meet the following objectives, which are relevant for KESS 2 East (KESS 2 about KESS 2 East, 2022):

- To increase the research capacity of small to medium enterprises (SMEs) by linking with a PhD or Research Masters project
- To encourage SMEs to undertake research and recruit researchers
- To prepare and train individuals to contribute to research as professionals
- To support the development of key technologies in the East Wales Area
- To promote higher-level skills development

The projects are tailored specifically to a research area that is of interest to the company partner, focusing on a real-world application. The projects generally focus on creating something tangible for the company to use or benefit from, whilst providing a rounded research experience for the student (*KESS 2 Knowledge Economy Skills Scholarships*, 2022)

The studentship was awarded by KESSII in August 2017 and began in February 2018 with the researcher, Zoe Cooke, named as the PhD student in the application and Director of Studies, Dr Ceri Phelps, as grant holder. The PhD was focused within the field of psycho-oncology, working in partnership with Tenovus Cancer Care (TCC), which is a Wales-focused cancer charity who provide support and clinical services to people affected by cancer (*The History of Tenovus Cancer Care,* n.d.). At the beginning of this research and prior to the COVID-19 pandemic, Tenovus Cancer Care provided a number of psychosocial interventions to people affected by cancer. As a consequence of the COVID-19 pandemic which fell during the time of this PhD, they had to reduce the services they offer and in a post-pandemic landscape now focus on their Nurse-Led Support Line, Sing With Us Choirs, Benefits advice, Tele-friend service and mobile clinical treatment services. Both research student and supervisor had previously worked with Tenovus on previous research projects within the field of psycho-oncology and the proposal underpinning this PhD evolved from the knowledge gained from that previous research. This knowledge, and the recognised difficulties of tracking and comparing the effectiveness of various psychosocial initiatives for those affected by cancer led to the following broad research question:

How can we best produce a user-friendly outcomes interface that will enable Tenovus and other organisations to rigorously evaluate the relative effectiveness and potential sustainability of psychosocial cancer support and prevention initiatives designed to improve the care of people affected by cancer across Wales?

The overall aims of the PhD identified in the initial research proposal for the studentship were as follows:

1) To identify, quantify and map core evaluation outcomes for psychosocial cancer initiatives

2) To develop and evaluate the utility of a bespoke computer database offering a user-friendly interface that does not require specialist knowledge or skills to navigate.

This chapter will provide a brief overview of the empirical context and rationale for this research before returning to more detailed research aims and objectives underpinning the different phases of research within this thesis at the end of this chapter.

The reason for the importance of this work is that the psychosocial impact of cancer on the individual and their family is well documented and evidenced by the large number of organisations across the UK that offer a range of clinical and psychosocial support and advice. The Wales Cancer Alliance is a coalition of 23 charities working to improve cancer services, prevent cancer, improve awareness that leads to early diagnosis and contribute to cancer policy (Wales Cancer Alliance, 2022). A small selection of cancer charities includes Tenovus Cancer Care who offer psychosocial and clinical support to people affected by cancer. Some examples of how they do this are through their tele-friend service, 'Sing With Us' choirs, clinical treatments delivered on their mobile chemotherapy units, and also provide practical financial advice through their money advice service. Another main charity within the Wales Cancer Alliance is Macmillan who provide cancer information and support to people affected by cancer. They offer information relating to different treatments, what to do when you've been diagnosed, how to access support and many more services. Finally on this short list of examples is Maggie's who offer free cancer support and information through their physical centres around the UK. Two of these centres are based in Swansea and Cardiff and provide support to those affected by cancer in the South Wales area. There are many more third sector organisations and charities who offer cancer disease specific support for breast, blood, kidney, bowel, children's cancers etc. The range of services being offered by these charities are either being evaluated at varying time points, superficially through qualitative feedback or not at all. The evaluative reports

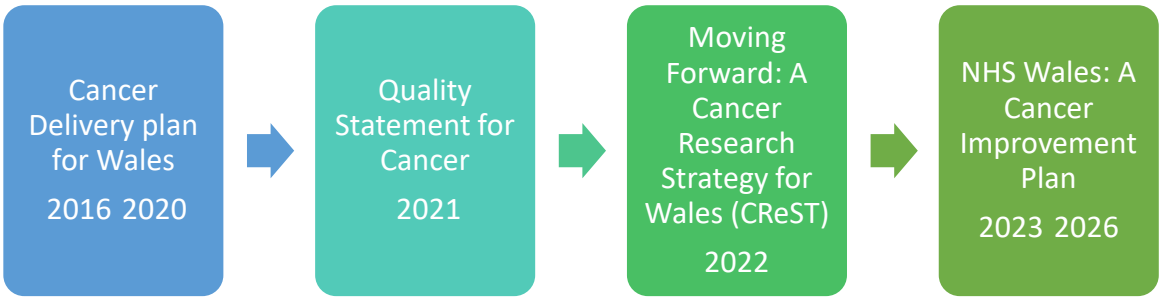
generated by Tenovus Cancer Care are more centred on the qualitative experience, which although has its place and provides a value to Tenovus, it does not facilitate a structured psychosocial evaluation and comparison across services which means they are unable to directly compare services to demonstrate their relative impact. This therefore becomes relevant to the work undertaken in this thesis as there is clearly an abundance of cancer support in Wales alone and there needs to be a way of ensuring these services best meet the needs of people affected by cancer in Wales. There needs to be structured psychosocial evaluations being conducted using the same key outcomes that allow services to be compared against each other and to generally measure the impact of these services on people affected by cancer.

Whilst advancements in diagnosis and treatment have resulted in higher rates of survivorship, this means that more people are living longer with cancer, creating an ever-increasing need for psychosocial support to deal with many challenges of living with a diagnosis of cancer, whilst also acknowledging those who are living with incurable cancer (WHO, 2021; Pizzoli et al., 2019). Many people who have had a cancer diagnosis experience a range of unmet needs, including reduced quality of life, and distress and fear of cancer recurrence (Mlakar et al., 2021). Therefore, to ensure the needs of these people are being met, it is essential to continually assess the level of unmet need and the support being provided to fulfil them (Mirosevic et al., 2019). A recent systematic review conducted by Mirosevic et al. (2019) noted that psychological factors and seeking information had the highest prevalence of unmet need amongst cancer survivors, especially in those who had breast cancer and those who had finished treatment within five years of being assessed. Supporting people with cancer during and beyond their diagnosis is paramount to reducing the prevalence of unmet needs and helping them cope with the impact of their diagnosis and treatment.

The Welsh Context: Cancer Care in Wales 2018 – 2026

Figure 1

Timeline of Cancer Policies 2018-2026



At the time of inception, this PhD was developed to align with the '*Cancer Delivery Plan for Wales 2016-2020'* agenda for achieving sustainable approaches to cancer care in Wales. This agenda was replaced with an interim policy released during the COVID-19 pandemic '*The quality statement for cancer'* published in March 2021, which aimed to build on the work outlined by the Cancer Delivery Plan for Wales and had a significant impact on cancer services. The quality statement focused on six areas of quality within cancer services: equitable, safe, effective, efficient, person-centred and timely. This PhD research focuses on aligning with the points outlined in this quality statement, specifically those which focus on improving psychological outcomes, increasing the use of patient-reported outcome measures, co-production of care to ensure the outcomes matter to those affected by and ensuring cancer services are measured.

Following this in July 2022, the *Moving Forward: A Cancer Research Strategy for Wales (CReST)* was published, with the aims to develop a more collaborative and efficient research community, which is hoped to increase grant funding revenue and will hopefully result in improving prevention, diagnosis and treatments for all patients with cancer. This policy aligns even stronger with the research undertaken within this thesis through the following points: building a collaborative research community which focuses on stakeholder engagement and partnerships, embedding research to meet the needs of people in Wales, and researching patient experiences and preferences for care. The CReST strategy identified six priority research themes, most of which focus on clinical cancer research and the work undertaken in this thesis would fall under theme six: '*Population health-based cancer prevention, early diagnosis, primary care & health services research*'. The strategy suggests that Wales needs to have a research ready environment and the work undertaken in this thesis aims to support Tenovus Cancer Care in having a research ready environment that they can use to evidence the impact and improve their services to people affected by cancer.

Finally, in January 2023, NHS Wales published *A Cancer Improvement Plan for NHS Wales 2023-2026* (Wales Cancer Network, 2023), which aimed to tie the interim policies together and move forward with tackling the state of the cancer landscape in Wales at this time. It is a collaborative effort between NHS, Wales Cancer Network and Welsh Government, to improve patient outcomes and reduce health inequalities in Wales. It outlines the actions that need to be taken by health boards and stakeholders to deliver the ambitions set out in the document. Following on from the Cancer Delivery Plan (2016-2020), there is still a clear focus on embedding Patient Reported Outcome Measures (PROMS) in clinical care to identify, monitor and treat the psychological and physical impact of cancer and its treatments. The new 2023-26 plan also discusses the importance of including patient experience as a key outcome when measuring quality of life by using

Patient Reported Experience Measures (PREMS). The Cancer Improvement plan (2023-24) regards patient experience or PREMS as a key outcome to be acted on, this has progressed from the Cancer Delivery Plan where it was only suggested to be embedded into clinical practice. This demonstrates the growing recognition and importance of the patient experience and how it can shape their care, and ultimately their health outcomes. Focussing on embedding PROMS and PREMS works towards one of the key themes identified in the Cancer Improvement Plan (Wales Cancer Network, 2023) that represents co-production of care, by collecting vital feedback from patients to ensure they can adapt services to meet their needs. The specific PROMS and PREMS are not detailed in the document, which leaves this open to interpretation. However, there is mention of using the Macmillan Holistic Needs Assessment (HNA) tool (Macmillan, n.d.) and the Distress Thermometer (DT; Roth et al., 2000), both of which act as screening and needs assessment tools. These are important tools for conducting a rapid assessment of distress or needs which contribute towards creating a personalised approach to that individuals care. However, the evolution of each plan discusses the need for a more in-depth assessment of an individual's quality of life, and embedding more of this into routine clinical care, again with no specific suggestions on how to do this. Additionally, there is a focus on signposting for emotional support, benefits advice and other holistic services to support the growing recognition that cancer care should be a collaborative approach, with multiple providers contributing to the cancer care pathway. This focus is emphasised the most in the updated plan, perhaps reflecting the post-pandemic cancer landscape. Overall the updated plan states that there should be a collaborative approach between the health boards in Wales and the third sector to ensure people affected by cancer are provided with emotional support and can access crisis care 24/7 by the end of 2026.

When reviewing each policy framework that has been developed from 2016 to 2023 it is apparent that there are common key themes running through them, but also

demonstrating the growing emphasis on patient outcomes and experience. Providing the best care for people affected by cancer is the key priority for all policies and this is encompassed in many ways. Focusing here on the non-clinical priorities, each document refers to the importance of co-production to agree a joint set of priorities between the policy makers and people affected by cancer. There is a large emphasis on PROMS and PREMS and how these need to be embedded into the clinical setting, however their importance becomes more significant through each updated policy. Early policy from the Cancer Delivery Plan (2016-2020) mentions how they need to start incorporating them, noting how useful they could be, and the updated policy for 2023-2026 describes them as being essential and must be acted on. Collaboratively across Welsh Government, NHS Wales and the Wales Cancer network, they want to develop a longer term, systematic and sustainable approach to embedding these tools to enhance service design, delivery and improvement.

When summarising the key priorities across the span of each policy from 2016 – 2023, there are some clear overlaps between those and the aims of the thesis. This is depicted in Figure 2, demonstrating that the work undertaken within this thesis aligns well with the goals set out by the Welsh Government and the Wales Cancer Network. Within the key priorities identified there are a number of which have been discussed throughout the thesis so far, but drawing particular attention to 'research ready environment'. This phrase is used in the *CReST (2022)* policy stating that health and social care should become 'research ready' environments to support researchers, clinicians and patients to take part in research now and in the future. This element aligns with this thesis because the tool being developed is to allow Tenovus Cancer Care to become more 'research ready' by enabling them to have an easy to access tool for evaluating the impact of their services.

Figure 2 *Overlapping priorities between the research aims of thesis and cancer policies*

Psychosocial interventions for individuals with cancer

Whilst Chapter two of this thesis provides a critical review of the range of support and psychosocial interventions available to individuals with cancer across the UK and beyond, it is important to briefly introduce the range and nature of initiatives designed to support people affected by cancer, including those with cancer and their family members. These may include tailored psychological interventions, informal support groups, psychoeducation, talking therapies, and online or telephone befriending services. The NHS and third sector or charity organisations are largely responsible for delivering these initiatives. This thesis does not focus on any clinical or pharmacological treatment interventions as it focuses on the psychosocial impact of cancer and interventions that have been developed to support people with cancer and clinical/pharmacological treatments fall outside of the remit of the researcher and the thesis.

As previously discussed, there are a large number of innovative cancer support initiatives being funded by charities and research organisations across the UK that are designed to support a wide range of people affected by cancer and prevention strategies

designed to educate the general public on changing lifestyle habits to reduce risk factors associated with developing cancer. Research has shown that early recognition and subsequent intervention for psychosocial problems can significantly reduce emotional distress in cancer patients. The National Institute for Health and Care Excellence (NICE, 2004) developed a four-tier model of psychological support for the care provided to cancer patients and their families. This four-tier model states that staff trained to a certain level such as Doctors, nurses and allied health professionals should be sufficiently trained to recognise and assess psychological health needs and provide an intervention where appropriate (Macmillan, 2015).

Psychosocial interventions are based on non-pharmacological treatments and support for individuals who have a cancer diagnosis and may be experiencing a negative impact on their overall health status (Galway et al., 2012). According to Macmillan, psychological interventions can be targeted at three different time points during the cancer journey, diagnosis, immediately following treatment and end of life care (Macmillan, n.d.). Similarly, Tenovus Cancer Care (2016) suggest that new and innovative models of psychosocial care and prevention strategies are required to support these individuals and their families, and to encourage the population to engage in preventative health behaviours to help reduce their risk factors of developing cancer.

Measuring the impact and effectiveness of psychosocial interventions for individuals with cancer

The methods used to evaluate interventions is discussed in detail in Chapter four, however the importance of evaluating interventions designed to support people with cancer will be briefly introduced here. With such a large number of unique and innovative cancer support initiatives being funded by charity and research organisations within the UK and beyond, there is a need to identify the most systematic and evidence-based ways of measuring the

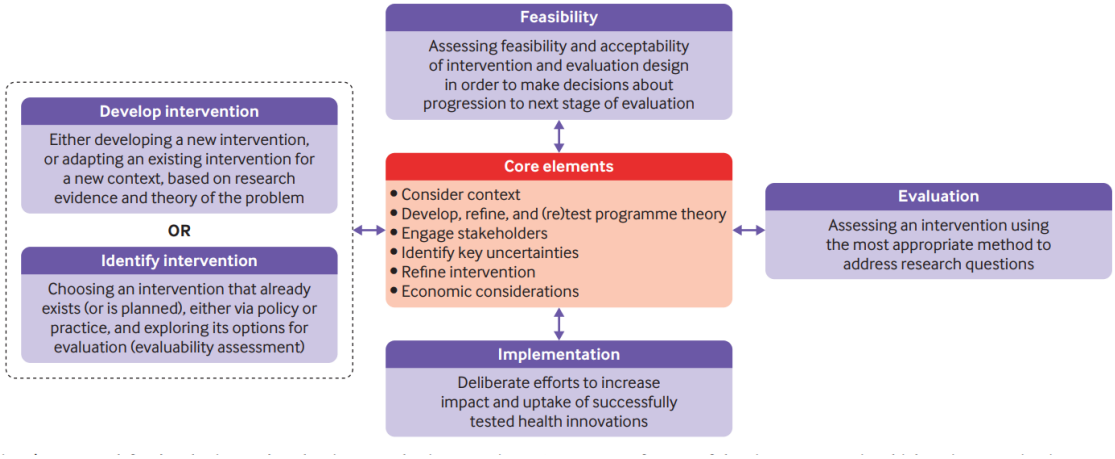
relative impact these initiatives have on a person affected by cancer. Identifying the most robust way of measuring key health outcomes allow data to be systematically collected, logged and mapped. Whilst many existing initiatives have been evaluated in terms of impact on cancer outcomes and experience (discussed further in Chapter two), these have tended to involve a broad range of methodologies and outcome measures that are rarely directly comparable. For the organisations that provide these services it makes it increasingly difficult to objectively quantify and compare the value of each initiative in terms of impact on core health and psychosocial outcomes. Having the ability to do this well would contribute to the sustainable delivery of cancer services and help to effectively support people affected by cancer. With the growing rates of people living longer with cancer, it is essential to develop something that allows a consistent and effective way of ensuring this support is having a positive impact on those individuals and that it best meets the needs of people affected by cancer.

When discussing the methods used to evaluate psychosocial cancer support, it is important to introduce the frameworks that underpin the development and evaluation of interventions. The Medical Research Council (MRC) have been providing guidance to support the development and robust evaluation of complex interventions since 2000 (Craig et al., 2008; Campbell, 2000) and has since published updated works up to the most recent framework published in 2021 (Skivington et al., 2021) in conjunction with the National Institute for Health Research (NIHR). The MRC framework (Figure 3) provides guidance to a broad range of researchers to enable to them to choose appropriate methodology to improve the quality of their research, how to understand their evaluation design and plan, and to subsequently enable them to develop the most robust intervention for the population and context they are working with (UKRI, 2021). The work conducted within this thesis can be mapped across some of the elements of this framework and addresses the changes within the new framework. The MRC framework is considered the gold standard for both

developing and evaluating interventions, and in the context of this thesis was used to support the methodological development of both the toolkit and it's on going evaluation.

The steps within the MRC framework as seen in Figure 3, depict the process from conception through to feasibility, pilot and/or evaluation. The work conducted in this thesis represents the conception, feasibility, pilot *and* evaluation of the psychosocial toolkit. The alignment of each phase of this thesis alongside the MRC framework is demonstrated in Figure 4.

Figure 3 *The MRC Framework*

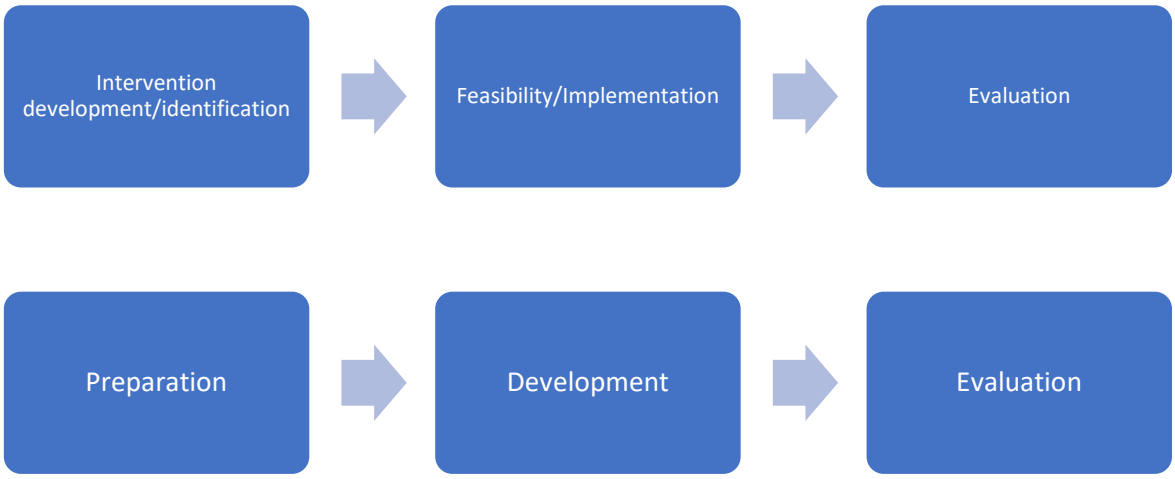


The context within the core elements:

Within the first 12 months of this PhD, a considerable amount of time was spent with staff, volunteers and service users of Tenovus Cancer Care. Time was spent getting to know each department from research and insight to service delivery/heads of services. It was important to understand the day to day operations of Tenovus from how they registered new services users and what process they went through, to how they conducted their internal service evaluations. During this time, Tenovus were in the process of migrating their client management system across to a newer, more intelligent system than they had been using. This was useful for the research as it allowed for an in depth insight into the wants and needs of Tenovus but also ensuring that there would be no duplication of information gathering from service users. Alongside spending time with staff and

volunteers within Tenovus headquarters, each of the services that were being delivered during this time were visited. This included the Sing With Us Choirs, mobile chemotherapy units, Support Line and the Money Advice Service. Being able to spend time with staff delivering services and speaking to people affected by cancer was an invaluable start to this research and helped shape the next phases. At this stage of the research it was clear to see that the rationale for the psychosocial toolkit and data visualisation interface was necessary for streamlining the evaluation processes at Tenovus and ensuring that this was accessible to more than just the research staff also became a priority.

Figure 4 *MRC Framework (top) and PhD phases (bottom)*



Feasibility

The MRC framework states that a feasibility study should be designed to assess predefined progression criteria that relate to the evaluation design, or the intervention itself. Within this body of work the final prototype which includes the psychosocial toolkit and research outcomes interface was piloted for acceptability and feasibility. The whole thesis represents a develop and test process, through engagement with stakeholders and consensus methods, user experience evaluation and a constant iterative process of feedback and adjustment. The early engagement with Tenovus as discussed earlier provided the

foundations for deciding whether this research was feasible. The MRC framework refers to an evaluability assessment which can be conducted prior to a feasibility study. The evaluability assessment mirrors the process undertaken to explore consensus and agree upon a set of psychosocial outcomes in which to evaluate the impact of an intervention for people affected by cancer. This process was undertaken prior to the final prototype undergoing a feasibility evaluation. The MRC framework also refers to economic modelling, although this was not part of this body of work, the rationale behind the research was to reduce costs for Tenovus and supports this element of the framework. This research aimed to provide a more efficient service by empowering Tenovus to evaluate which of their services were performing better at improving the psychosocial health of people affected by cancer. By doing this it could contribute to funding decisions when reviewing service delivery. Therefore, this research and final product facilitated a better economic model of service delivery and evaluation.

Evaluation

The MRC framework states that the most important aspect of evaluation design is the choice of outcome measures. This body of work represents that process of choosing outcome measures in a systematic and informed manner. Evaluation has typically focused on 'does this intervention work as it was intended to' which ignores any wider impact that these interventions could have on an individual or population. The real-world implication of the psychosocial toolkit developed in this body of work allows Tenovus to not only evidence whether or not their interventions are working but to understand what other impact it has had on an individual and where there may be short comings within the service. For example, if Tenovus were to see high levels of loneliness which did not reduce following engagement with one of their services, then this could be something they could implement as part of ensuring the needs of people affected by cancer are met. For this research, feasibility and evaluation overlap due to the methods used throughout. As well as

piloting the psychosocial toolkit in a real-world setting, the research outcomes interface was subjected to multiple steps of user experience evaluation to ensure it was fit for purpose and to allow feedback to be implemented. Overall, the evaluation focuses on assessing an intervention using the 'most appropriate method' which in this body of work is determined by a systematic and population informed approach.

Implementation

This phase is where the real-world implementation of an intervention is considered. Questioning how something will work in practice, considering whether there are any barriers and how they could be overcome. These barriers may have been identified during the feasibility phase where the intervention has been tested and subsequently adapted. As an actual product was being developed for this research, it was important to consider exactly how this could be implemented and what the process would be for that. The users of the product were considered alongside building in time for training and hand over of and to the Tenovus staff.

Based on the above, the next section will detail the aims and objectives of this PhD based upon the context given surrounding cancer care in Wales, the need for embedding good quality PROMS within cancer care and supporting the third sector with achieving a research ready environment. With the support of the MRC framework this thesis will detail the practical approach taken to achieving the aims of this research.

PhD Aims and Objectives

Returning firstly to the overall aims of this PhD studentship, this penultimate section will detail the specific research objectives of each phase of the PhD.

Overall aims:

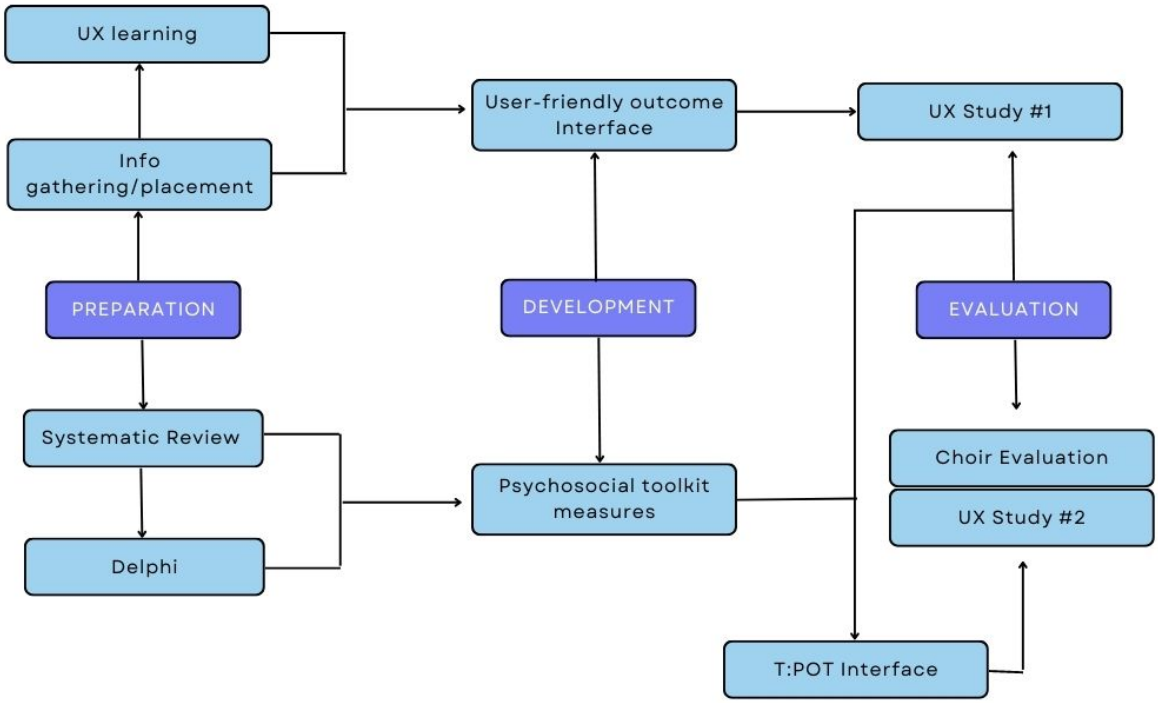
1. to identify, quantify and map core evaluation outcomes for psychosocial cancer initiatives and secondly,
2. to develop and evaluate the utility of a bespoke computer interface offering a user-friendly interface that does not require specialist knowledge or skills to navigate.

Structure of the thesis:

The overall structure of this thesis begins with introduction to the literature surrounding the psychosocial impact of cancer and interventions designed to support individuals affected by cancer. This chapter will critically discuss the types of interventions available and will critically review the theories of how people cope with stress and chronic illness. Chapter three discusses the range of methodologies used within the thesis, exploring the philosophical positioning and underpinnings of the research that has been conducted and the justification for each methodology, explaining how each one compliments or contributes to the next phase. Chapter four is a systematic review of the existing patient reported outcome measures (PROMS) validated on a cancer population and a critical examination of their methodological quality in order to determine the most psychometrically robust outcome measures to take forward into the next study. This directly contributes to the development of the empirical study conducted in chapter five, which details the Delphi consensus building study. The Delphi consensus building study involved key cancer stakeholders to explore and establish consensus on which of the constructs identified in the systematic review were the most relevant and important when evaluating the psychosocial impact of a cancer support intervention. Chapter six details the

second empirical study which examines the user experience and usability of the data visualisation interface that was developed, as well as detailing the process involved in the design and creation of the interface. This phase of the PhD was heavily collaborative with the involvement of an external partner who specialise in developing this type of software. Chapter seven discusses the last phase of the research which details the development of the 'psychosocial cancer evaluation toolkit' which details how the results of the systematic review and Delphi consensus study contributed to the development of the toolkit. It also details the pilot study conducted to test the feasibility of the toolkit in an applied setting, which in this case was with people with a cancer diagnosis who engaged with Tenovus Cancer Care's 'Sing With Us' choirs. The final chapter of this thesis is an overall critical discussion of the research conducted throughout this PhD studentship, ending with the impact it has had and any potential future directions.

Figure 5 *PhD Overview and interconnections*

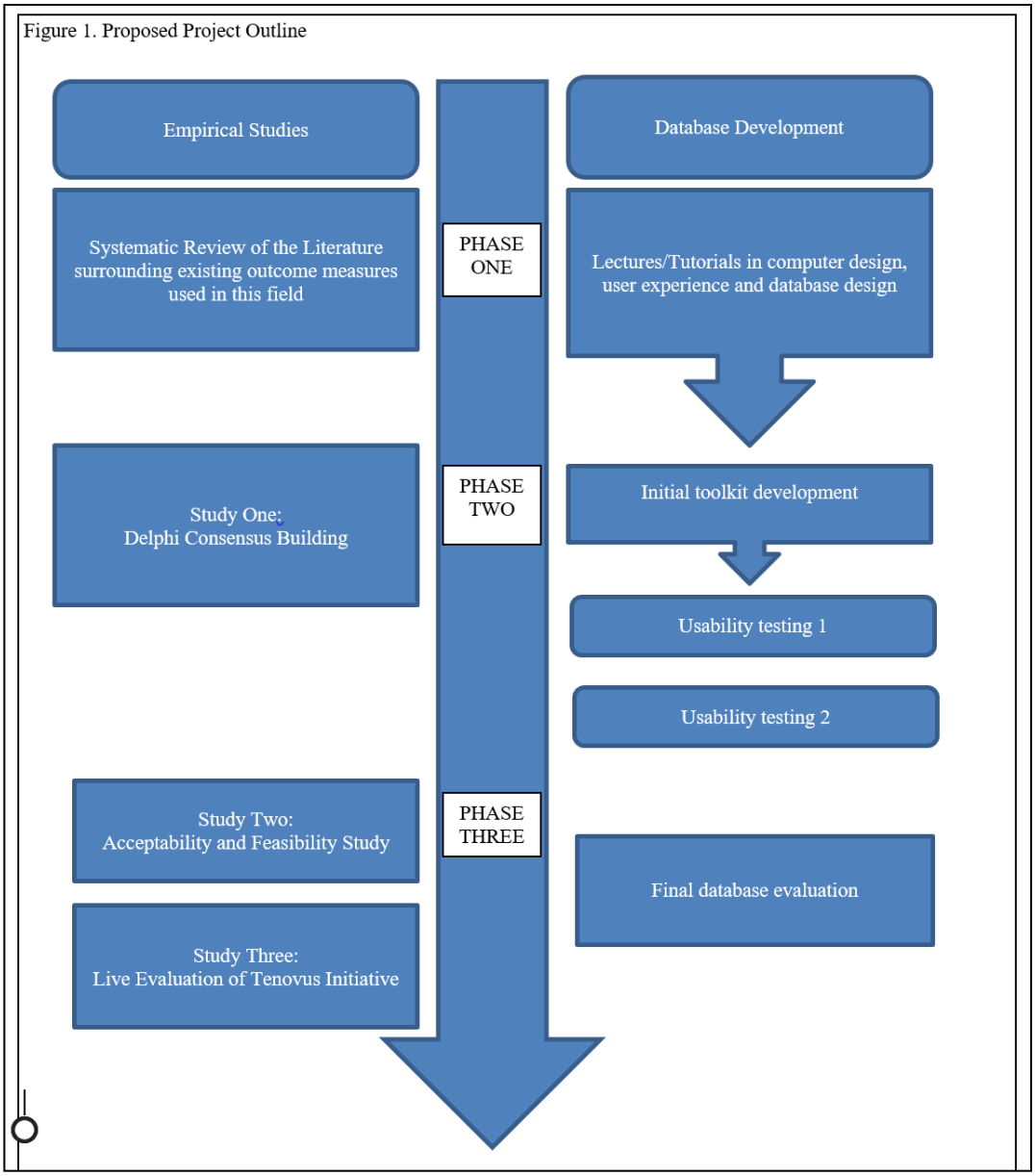


The research contained within this thesis can be divided and mapped out into three main phases: Preparation, Development, and Evaluation. The initial proposal had always planned for this research to be conducted in three phases (see Figure 6 for original plan) with the understanding that the final phase, and studies within that phase were subject to change based on what had been found throughout the research. There are minor differences between both figures with the most recent (Figure 5) giving a more accurate representation of how each element of the research links together, specifically how the psychosocial toolkit and user-friendly computer interface link together and become one final product. Figure 5 depicts how each phase contained parallel activities that then contributed to the next phase and how each of these methodologies intertwine. In the preparation phase the systematic review and Delphi study were conducted to build the solid foundation for the psychosocial toolkit. Alongside this, the KESS mandated work placement hours at Tenovus Cancer Care and engagement with Applied Computing university modules also took place providing a knowledge of a) the inner workings and vital understanding of

Tenovus Cancer Care and the services they provide and, the knowledge needed to understand the applied computing, user experience evaluation element of this research. Both arms were essential for preparing for the development of the toolkit and the development of the computer interface. The final phase is where each element of the research was tested in order to establish whether it was fit for purpose and could achieve the initial objectives set at the beginning of this research. The evaluation phase contained many parts working in parallel to bring everything together into a final evaluation of a Tenovus service using the Tenovus: Psychosocial Outcomes Toolkit (T:POT) interface. The chapters that follow will provide an in-depth explanation of what was conducted and a critical review of what was found, how each method of data collection or development was triangulated to achieve the initial objectives. The thesis will finish will a critical discussion on how well each of these methods worked, how well the data is supported by the literature that preceded and what the research contained within this PhD thesis contributes to the knowledge base of psycho oncology and the psychosocial evaluation of cancer support services. Finally, a reflection on the COVID-19 pandemic and how this changed the course of this research and impacted some of the decisions made, allowing room to discuss efforts made to overcome this impact and the journey taken to reach the final objectives. As a reminder, Figure 5 and 6 and the explanation above aim to demonstrate how the overall objectives were achieved which were:

1. to identify, quantify and map core evaluation outcomes for psychosocial cancer initiatives (Psychosocial Toolkit/T:POT)
2. to develop and evaluate the utility of a bespoke computer interface offering a user-friendly interface that does not require specialist knowledge or skills to navigate. (T:POT interface)

Figure 6 *The initial proposed project outline in 2018*



Chapter Two: A critical review of the literature

The research undertaken in this thesis rests on the understanding gained from the breadth of research that exists already that a cancer diagnosis has a significant impact on persons psychological, social, emotional, spiritual, and mental wellbeing. The following chapter will detail the research surrounding what the psychosocial impact is on individuals who have been affected by cancer, the theory that helps us understand how individuals respond and cope with an illness like cancer, a critical review of the existing psychosocial interventions that have been designed to help improve the psychosocial health of people affected by cancer and lead onto the importance of evaluating interventions and the issues that are faced in the cancer field. This chapter forms part of the preparation phase as described in Figure 5.

Search strategy

Electronic searches were performed in the University of Wales Trinity Saint David (UWTSD) library system, Google Scholar and Research Gate. There were multiple points of investigation for this literature review which are referred to throughout but that required multiple searches. Databases included within the UWTSD library system included; Pro Quest, Pub Med Central, Science Direct, Directory of Open Access Journals, SAGE, Springer Link, APA PsychBooks and PsychArticles. Table 1 shows the keywords associated with each overall topic of enquiry.

Table 1

Search strategy

Overall topic of search	Keywords and/or phrases
Cancer statistics Cancer policy Welsh cancer context	Prevalence of cancer (UK/Worldwide/Wales) Welsh cancer statistics Cancer policy documents Cancer policy AND covid
Theories of stress and coping	Stress AND coping Coping with cancer Coping theory Coping AND cancer
Psychosocial impact of cancer	Impact of cancer Psychological consequences of cancer Consequences of cancer Cancer AND distress Cancer AND mental health
Cancer and Covid-19	Cancer AND COVID-19 Cancer AND pandemic Pandemic AND healthcare

Current prevalence and incidence rates of cancer: the global, UK and Welsh context

The latest statistics available at the time of finalising this PhD thesis indicate that cancer remains a leading cause of death worldwide, accounting for nearly 10 million deaths in 2020 alone (WHO, 2022). In 2020 the Global Cancer Observatory (GLOBOCAN) reported over 19million cases of cancer had been registered in 2020 alone (Sung et al., 2021). The most commonly diagnosed cancers are breast (2.26m cases), lung (2.21m cases), colon and rectum (1.93m cases) and prostate (1.41m cases). Whilst breast cancer rates have surpassed lung cancer in 2020, lung cancer remains the leading cause of cancer deaths globally (WHO, 2022; Sung et al., 2021; GLOBOCAN, 2020). In 2021 UK-based cancer charity Macmillan reported that there are around 3million people reported to be living with cancer in the UK alone, with this number expected to rise to over 5million

by 2040 (Macmillan, 2021). Based on these reported cases, it is estimated that someone is diagnosed with cancer every 90 seconds in the UK. Looking further to the Welsh context, in 2020 it was estimated that there were around 170k people living with a cancer diagnosis, estimated to rise to around 300k by 2020. Although these rates are expected to rise, they reflect people currently living with cancer, which can be attributed to the aging population but also the advancements in early diagnosis and treatments leading to more people surviving cancer (Macmillan, 2021).

Having introduced the current state of play with cancer statistics globally, in the UK and in the Welsh context this chapter will end with a review of existing approaches to measure the impact of a cancer diagnosis and the effectiveness of cancer support services designed to support these individuals. The statistics tell us that the rate of cancer diagnoses continue to rise (CRUK, 2020), however people are living longer with cancer due to advancements in treatments, screening programs, and an increase in signs and symptom awareness. In order to understand why more people living longer with cancer may be an issue, the following literature will review the evidence for the psychosocial impact of receiving a cancer diagnosis, exploring also those may be living with incurable cancer. It is important to recognise the consequences of a cancer diagnosis and its associated treatments may have on individuals, especially if they are to survive and continue to live with or beyond their diagnosis (Hulbert-Williams & Kennedy, 2015).

Individuals who have received a cancer diagnosis and have been through the intense treatments associated with it, often experience long-term mild to moderate psychological issues (Macmillan, 2013) and a cancer diagnosis in general can have a substantial impact on mental health and wellbeing (Niedzwiedz et al., 2019). The way in which we measure the impact of a cancer diagnosis is by examining a number of different health constructs. One of the key health constructs within the field of psycho oncology is quality of life (QoL). According to the World Health Organisation (WHO, 2016) QoL is a

term used to describe the overall physical, emotional and social wellbeing of an individual and is one of the most commonly measured health outcomes in the cancer field (Dehkordi et al., 2009). This is especially relevant when measuring the impact of a cancer diagnosis or measuring the effectiveness of an intervention that has been designed to improve the psychosocial health of individuals affected by cancer. A large amount of empirical research has typically evidenced that individuals living with a cancer diagnosis are more likely to experience poorer quality of life and higher levels of anxiety and depression compared to those without cancer (Williams et al., 2016) and those from a vulnerable population or lower SES community are even more likely to experience even poorer QoL outcomes (Mlakar et al., 2021).

Distress is a generic term used to embody a variety of psychological responses including depression, anxiety, fear, worry, anger or panic which all contribute to overall levels of distress amongst people with cancer (Kirk et al., 2021). Distress amongst people with cancer can initially be a response to their diagnosis but may persist throughout their cancer trajectory (Hamilton et al., 2018). It is not uncommon for individuals with cancer to experience any of these levels of psychological adjustment, however it is also expected to be present in cancer survivors following primary cancer treatment (Andrykowski, Lykins & Floyd, 2008). The psychosocial needs of cancer survivors can vary drastically to those who are newly diagnosed or still undergoing treatment, as survivors have been found to experience both positive and negative levels of psychological adjustment, by displaying factors related to posttraumatic growth, such as a greater life meaning, enhanced self-esteem and purposefulness (Cordova, 2001). Focusing on anxiety and depression and these are the two most commonly reported psychosocial problems in cancer patients, rates of which are around 30% higher than that of the general population (Pitman et al., 2018). A systematic review and meta-analysis by Hashemi et al., (2020) explored the prevalence of anxiety amongst breast cancer patients and found 41.9% of women across 36 studies

experienced anxiety during or after their treatment for breast cancer. A review by Neidzwiedz et al., (2019) examined the prevalence of depression in those living with and beyond cancer, they found depression is present in around 13% of cases when using diagnostic clinical interviews and increases to 49% when using all other assessment methods such as validated psychometric scales. A study conducted by Kirk et al., (2021) explored levels of psychosocial distress amongst a cancer population, assessed using the Distress Thermometer (DT) and found over 56% of the sample (n= 1.071) reported severe distress (a score above 7). They then identified a list of factors associated with the risk of increasing levels of distress amongst a cancer population and found that depression, sadness and a lack of control over treatment options were significantly associated with higher levels of distress in this sample.

It is clear from the evidence discussed above that a cancer diagnosis has a significant negative impact on an individual's psychosocial wellbeing. The following section will explore the models and frameworks which help us understand why people respond to illness in this way and how they attempt to cope with the impact. A cancer diagnosis and its associated treatments are considered stressful live events, often resulting in acute stress and significant life change (Anderson, 1994; Guner et al., 2006). There are many biological models that explain what impact stress has on the body, however the models being examined here help us understand how the body then copes with that stress in both physical and psychological mechanisms when faced with the threat of illness such as cancer. The first model being explored is the Transactional Model of Stress and Coping (Lazarus, 1966; Lazarus & Folkman, 1984; Folkman & Lazarus, 1988) which provides an understanding of how people form a coping response to a threat based on what resources they have available to them. This will then determine how well or not they cope with that threat. The second model to be explored is the Common-Sense Model of Self-Regulation applied to health and illness (CSM, Leventhal et al., 1980) which helps to understand the

beliefs and representations people form about their illness and the coping behaviours they engage with.

It is clear from the significant body of evidence that cancer has a negative physical and mental impact on an individual from the side effects of the cancer itself and any associated clinical treatments, in addition to worries about death and dying and a change in relationships within a person's life all contribute to a heightened sense of strain. Stress can manifest as physiological, cognitive, emotional and behavioural responses linked to the way in which individuals cope. Coping is defined as the way in which individuals deal with a potentially threatening or harmful situation (Carver & Vargas, 2011) and coping strategies are the thoughts and behaviours people engage with in response to the stress, these can manifest both positively and negatively. When confronted with the threat of an illness such as cancer, individuals will usually start to form a stress response to determine dealing with the threat and whether they believe they have the capabilities to cope with it (Bowman et al., 2003).

The Transactional Model of Stress and Coping

The Transactional Model of Stress and Coping is one of many models that attempts to draw the links between stressful events and coping. The model was proposed by Lazarus and Folkman in 1984. The model suggests that a person's ability to cope with a stressor is a direct consequence of the interactions that occur between them and their environment and was developed to further examine the role of emotional reactions to a stress response and how this affects a person's ability to cope. Lazarus and Folkman's transactional theory of stress focuses on perceived stress, appraisal and coping **(**Lazarus & Folkman, 1984) describe stress as a two-way process including two functions, the production of stressors from the environment and the response of the individual subjected to these stressors. The role of cognitive appraisal as described by Lazarus and Folkman is described as the individuals perceived threat of the stress and the assessment of resources required in order to reduce,

tolerate or eliminate the stressor and the stress produced. Lazarus and Folkman (1984) break cognitive appraisal down into primary and secondary appraisal. The process of primary appraisal allows the individual to classify whether the stressor or situation is a threat or challenge. When the stressor is viewed as something that could cause future harm, it is viewed as a threat, if it is viewed as a challenge, a person will develop a positive stress response. Secondary appraisal refers to the feelings associated with dealing with the stressors, positively and negatively framed affirmations can shape how the individual will respond to the stressor (Bigatti, Steiner & Miller, 2012).

This model can be a useful framework for understanding the psychosocial impact of a cancer diagnosis. A cancer diagnosis will typically elicit appraisals of threat which can be associated with anticipated future harm and consequently feelings of anxiety and depression. In the instance where an individual perceives the diagnosis as something to overcome then they will elicit challenge appraisals. Appraisals matter because of their relationship to health outcomes. Bigatti, Steiner and Miller (2012, building on previous work from Gallagher, 2002) explored the relationship between cognitive appraisals, coping strategies and depressive symptoms in the same cancer population (women with breast cancer) and found that higher appraisals associated with harm or loss and greater use of avoidance coping were predicted to have higher depressive symptoms. They found that cognitive appraisals made at two months post diagnosis predicted 40% of the variance in depression at six months in cases of women with breast cancer and that women who perceived their breast cancer as a threat and lacked confidence in their ability to cope, reported much higher depressive symptoms. Cognitive appraisals were measured by the Cognitive Appraisal of Health Scale (CAHS; Kessler, 1998) which assessed primary appraisals of threat, harm, loss and challenges, the CAHS is a well-established scale and is reported to measure actual cognitive appraisals rather than constructs relating to them. The authors reported acceptable to good reliability scores using this measure (α=.76-.88) and to measure coping they used Lazarus

and Folkman's (1998) Ways of Coping questionnaire which has slightly lower reliability scores (α = .61-.79) but still meets an acceptable level of reliability. The results of this study are unable to be generalised due to the small sample size and lack of diverse demographics and therefore this may represent parts of the population. However, it does provide some basis for enhancing the knowledge about understanding the role of cognitive appraisal and coping.

Further research conducted by Obbarius et al., (2021) tested a modified model of the Lazarus and Folkman transactional model of stress and coping on a sample of psychosomatic inpatients. They focused on the person-environment interaction in order to see how much this accounted for the individual stress response in a group of psychosomatic inpatients. Using self-reported measures they examined resources, sense of coherence, self-efficacy and optimism, perceived stressors, coping, stress response and psychological well-being to test the model. Their testing supported the idea that resources and perceived stressors have an impact on the overall stress response and this in turn affected psychological well-being by predicting levels of depression. The results provide support for strengthening psychological resources in order to benefit psychological wellbeing, which is relevant to the development of psychosocial support interventions. It is interesting to note that Obbarius et al., (2021) removed coping from their model following the first test as they found that the measurement tools for coping did not fit the data well enough and their model performed better without it. This is unsurprising as it is reported throughout the literature that coping is a difficult construct to measure and quantify due to their being multiple types of coping strategies and that this is a very individual process. Following this, their suggestion was that self-reported coping measures could benefit from being revised in order to strengthen their relevance. This links to some previously written work by Lazarus who criticised the strength of self-reported measures as a whole and that they may not be as scientifically reliable as clinical, or more quantitative measures.

The Common-Sense Model of Self-Regulation (CSM)

Stress can be considered as a person's physiological, cognitive, emotional and behavioural response to a threatening situation. Coping is often defined as the way in which individuals deal with a potentially threatening or harmful situation (Carver & Vargas, 2011), it includes cognitive and behavioural strategies that attempt to reduce the actual threat, or the negative feelings associated with it. When confronted with a cancer diagnosis, therefore, individuals will usually start to think about the process of dealing with the stressor and whether they have the capabilities to cope with it (Deimling et al., 2003; Lazarus & Folkman, 1984**).** As a chronic condition, coping with cancer is therefore an ongoing process involving constant efforts and the attempt to evaluate the success of these efforts.

There are a number of models available in the literature to explain how people cope with stress and illness, the following section will focus on understanding how people form responses to illness using the Common-Sense model of self-regulation (CSM or Self-Regulation Model, SRM). This was first developed by Leventhal and colleagues in 1980 and has continued to publish multiple works since, some of which will be referred to throughout. The CSM provides a conceptual framework for understanding the processes involved in a person's appraisal of health threats. It allows us to understand the cognitive and behavioural underpinnings of an individual's representation of their health and illness and how they may form responses based on these processes (Leventhal et al., 2016). When thinking about applying this framework to the cancer population it allows patients to act as 'common-sense scientists' to manage their condition and make sense of their cancer and associated symptoms and threats (pp.373, Benyamin & Karademas, 2019).

Whilst incorporating aspects of the coping and appraisal process identified by Lazarus and Folkman (1984) it goes beyond this to also consider that there is a direct relationship between illness representations and coping behaviour and provides a

framework for predicting adherence to treatment and lifestyle changes, which is particularly useful for designing interventions that are targeted towards improving a variety of health outcomes (Leventhal et al., 2016). Additionally, understanding an individual's capacity to respond to illness threat information is useful for encouraging engagement with preventative health strategies such as screening programmes (Hagger & Orbell, 2022). When faced with a health threat, people will form a cognitive representation and an emotional response based on their beliefs about the individual dimensions of the CSM. The CSM has five key dimensions: identity, cause, consequences, timeline and control, with a later addition of emotional representation (Moss-Morris, 2002). The way in which individuals form these cognitive and emotional representations of illness is influenced by stimuli which include, personal experience, media, family and friends. Any of these or a combination of these stimuli can influence how the individual decides to cope with the stressor which can influence any potential preventative behaviour e.g., help seeking, adherence to treatment and engagement in self-care behaviour.

The five dimensions of the CSM as briefly mentioned above are expanded below to include more detail and how these can be understood in the cancer context.

Identity *– the label of the health threat and its symptoms (cancer and its side effects)*

Cause *– individuals' beliefs about the cause of the health threat (genetics, health risk behaviours)*

Timeline *– the perceived timeframe of disease development, duration, and recovery*

Consequences *– the imagined and real beliefs about what effect the health threat may have on their life*

Curability/Controllability *– the degree to which someone believes the health threat can be controlled or cured by themselves or others. This later becomes personal and treatment control.*

These five dimensions are just the beginning of understanding an individual's response to a health threat. The perception of health threat stimulus simultaneously triggers problem-focused self-regulation and emotion-focused self-regulation, e.g., physical symptoms or side effects of cancer can initiate feelings of panic or worry (emotional response). Being aware of these cues help to activate a help-seeking response (booking a GP appointment or confiding in a friend about the worries). The outcome of this process then allows us to see whether the emotional response (panic and worry) has been alleviated by engaging in a help-seeking behaviour. If successful, this provides a feedback loop that allows a positive coping response to be formed when faced with another stimulus. With the base of the CSM explained, an extended model of the CSM was proposed by Hagger and Orbell (2021) who critiqued the evidence behind the CSM due to the focus on correlations between the dimensions of illness representations and illness and coping outcomes. In their conceptual review they concluded that the research typically reports that the illness representations with a high level of health threat (consequences, timeline, cause, identity, emotional representations) are usually positively correlated with maladaptive illness outcomes such as anxiety, poor quality of life and illness progression. Whilst the dimensions of the CSM that represent a much lower health threat and the individual's belief in controllability (personal control, curability etc.) are negatively related to these outcomes. For example, for those individuals who attribute their illness to something that is within their control e.g., diet or lifestyle related, they are less likely to have poorer health outcomes and adopt adaptive coping behaviours. The extended model proposes adding constructs that facilitates a greater way of explaining the relation between lay representations of health threats, coping responses and illness outcomes.

Hagger and Orbell's (2021) proposed extended model first aims to formally operationalise some of the key processes identified in Lazarus and Folkman's original model and proposed some additional constructs that provide a more in-depth explanation

for the interaction between a person's lay representation of a health threat, their coping response and their illness outcome. The additional constructs include beliefs about specific coping behaviours as predictors of coping, alongside illness presentations, beliefs about treatment (effectiveness, concerns and side effects) and socio-cultural constructs like socio-economic status and ethnicity. The model as a whole addresses the issue of measuring coping, and defines coping as coping strategies and improved psychological health outcomes. By improving psychological health outcomes it can suggest a person is coping with their illness or that their coping strategies have strengthened. Hagger and Orbell specifically suggest that coping should be measured as *any* procedures in which an individual has adopted to manage or treat their health threat. These procedures may involve specific behaviours aimed at managing the health threat or avoiding the emotional response to the health threat or problem focused and emotion focused.

Hagger and Orbell's (2021) extended model aligns with the updated MRC Framework (Skivington, 2021) as Hagger and Orbell suggest that *any* attempt at managing a health threat is a valid coping mechanism. Additionally, the new MRC framework guidance now includes non-theory based interventions as valid psychological interventions, meaning that the ways in which people cope could be measured more broadly, perhaps just by measuring the improvement in their psychological health outcomes. This is important given the context provided above linking the aims of this thesis to the priorities identified in the relevant cancer policies. Cancer support services are not always complex theory-based interventions and thus being recognised as a valid intervention supports the rationale that all services should be evaluated to ensure they are best meeting the needs of people with cancer.

A critical review on the role of coping and measurement in health psychology

Based on the models above it can be better understood how people appraise a stressful situation and how they may cope with the stressor. Based on the works by Lazarus

and Folkman's model of stress appraisal, the three main definitions of coping are Problem-focused coping (PFC), Emotion-focused coping (EFC) and Meaning-focused coping (MFC), coping flexibility, and will be referred to throughout in their abbreviated form A key criticism within the coping literature is the conceptualisation of coping how researchers can accurately measure how effectively a person is coping with a stressor. One of the main considerations within the coping measurement literature is whether coping is defined by coping styles or coping as a response to a stressor.

Lazarus and Folkman (1984) proposed that there are two main strands of coping strategies: problem-focused coping and emotion-focused coping, with Folkman (1997) later adding meaning-focused coping. Problem focused coping and emotion focused coping can be distinguished by their immediate responses to a stressor, focusing on the problem then the emotion respectively. Meaning-focused coping is associated with focusing on positive well-being and often reserved for when situations are chronic and will not resolve. Regardless of response strategy, Folkman (1997) describes effective coping as the coping that is associated with the desired outcome, which would be the outcome in which the individual was intending e.g. less worry, less stress, less anxiety or fear of dying.

Whereas Heffer and Willoughby (2017), further discuss the premise of coping flexibility, which describes an individual's ability to modify and change coping strategies depending on the context. Stress and coping theories focus on the assumption that successful coping is demonstrated by an individual's ability to adjust and change their coping strategies in a way that elicits and facilitates positive outcomes (Cheng et al., 2014). Coping flexibility offers a way of studying coping responses by monitoring an individual's ability to adapt and change depending on the stressful situation they are presented with and the diverse range of coping strategies that they possess. From the research on coping flexibility and its application to the cancer field, it seems that it may only be applicable to adaptive coping mechanisms and does little to identify negative adjustment. It is hoped that

the work undertaken in this thesis aims to encompass all positive and negative coping adjustments as a representation of coping flexibility. Typically PFC is aimed at resolving the stressful situation and working out ways to diminish the stressor. The strategies associated with PFC usually take the form of information seeking, the removal or reduction of stressful stimuli, planning and taking direct action (Carver, Sheier & Weintraub, 1989) and generally taking control of the stress (Carroll, 2013). This means that PFC largely allows for the evasion or reduction in the threat of the stressor (Carver & Vargas, 2011) by evaluating the pros and cons of potential outcomes and what actions can be taken (Lazarus & Folkman, 1984). Research from Matthews and Cooks (2009) has shown that PFC is correlated with emotional well-being in early-stage cancer diagnoses, due to the usually shorter timeframe between diagnosis and treatment and subsequent success rate in treating the cancer. Recent research into the assessment of coping styles and the relationship to anxiety within cancer patients was explored by Michalowska, Matusewicz and Samochowiec (2019). They found a significant relationship between task-orientated coping (PFC) and state anxiety, where the increased use of task-orientated coping reduced levels of state anxiety and reduced use of task-orientated coping increased state anxiety.

Moving on to EFC which reflects when a stressor elicits distress emotions (Carver & Vargas, 2011) and the strategies are usually defined by the actions taken to manage the emotional distress caused by or associated with the stressful event (Lazarus & Folkman, 1984). EFC manifests in behaviours such as venting of emotions, seeking out social support, denial, relaxation exercises and mindfulness based techniques (Carver & Vargas, 2011). Positive appraisal within EFC has been linked to positive self-perception and life meaning within cancer survivors (Schroevers, Kraaji & Garnefski, 2011). Additionally, positively reframing the cancer diagnosis as a challenge to overcome, has been positively linked to greater well-being and lower distress (Degner, Hack, O'Neill & Kristijanson, 2003). Adding to the research on EFC; Michalowska et al., (2019) found a significant

relationship between EFC and state anxiety, an over reliance on EFC resulted in increased levels of state anxiety. They found that patients with low and moderate levels of anxiety were more likely to use EFC compared to those with higher levels of state anxiety who found more benefit from using task-orientated coping (PFC).

The research typically points towards problem-focused coping strategies being more effective than emotion-focused strategies. Problem-focused coping generally results in a positive outcome, whereas the variation in emotion-focused coping strategies means that there can be both positive and negative outcomes. Negative outcomes and negative coping strategies can be linked to avoidance coping which is generally a total avoidance of dealing effectively with the stressor and its impact. Denial (as part of emotion-focused coping) is strongly linked with avoidance coping and illness beliefs. If an individual is in denial about the severity of their illness, they are less likely to engage in problem-focused coping strategies (Baker, Berenbaum, Howard, 2007). In the literature, coping is generally accepted as a complex process. Many models of stress and coping are discussed in the literature, but ultimately individuals report using a mixture of coping strategies when faced with a stressor (Lazarus, 1993).

Moving on to MFC (Park, 2010), this style of coping is proposed as another strand of coping appraisal which is defined as making new meaning following a highly stressful situation and focusing on finding a positive meaning from the stressful situation. Amongst the research surrounding survivorship, it is often found that individuals struggle to cope with the psychosocial consequences of cancer and usually experience feelings about a fear of death, isolation and life meaninglessness. Some survivors take almost an opposite path through the process of MFC. It is found that survivors using this coping strategy often report better psychological well-being, a stronger feeling of resilience and are more invested in their futures (Henoch & Danielson, 2009; Ussher, Kristen, Butow & Sandoval, 2005 cited in van der Spek 2013). MFC has also been explored within the palliative care

phase of the cancer journey with some studies reporting that individuals showed improved self-esteem, sense of purpose, optimism and less suffering following a psychological intervention (Cohen et al., 2006; Chochinov et al., 2005; Breitbart et al., 2010; Giese-Davis et al., 2002; Bordeleau et al., 2003; Classen et al., 2001; Spiegel & Spira, 1991). Adding to this area of the literature; Spek, Vos, Uden-Kraan, Breitbart, Tollenaar et al., (2013) conducted a series of focus groups exploring MFC amongst cancer survivors. Focus group discussions found that there are multiple ways of finding meaning. Meaning is thought to be experienced through relationships (feeling a stronger connection to family members or partners), experiences (exploring and finding more enjoyment in nature), creativity (expressing themselves through arts, crafting etc.) and work (being successful and committed). Some participants talked about the idea of 'leaving a legacy' as a way of MFC, rather than fear death or recurrence they took the opportunity to pass on their knowledge to others (in a work-related situation). Overall, they found that cancer survivors in general experience more meaning in life after cancer than before their diagnosis. MFC may have a positive impact but it has been found that *searching for meaning* (Hoffman, Lent & Raque-Bogdan, 2012) is related to poorer psychological health outcomes, found in men with prostate cancer (Roberts, Lepore & Helgeson, 2006) between the end of treatment and first follow up and in women with breast cancer (Tomich & Helgeson, 2002) who reported searching for meaning more than five years post diagnosis. Both groups reported more negative affect and reduced mental functioning. Overall, the research surrounding MFC suggests that although it has a positive impact on cancer survivors, if people become too focused on finding meaning following their diagnosis this could end up having a negative impact on their psychological recovery.

Although the above presents an overview of three of the coping categories, one of the key criticisms remains of how difficult it is to measure coping due to the lack of consensus on the core categories that define coping. Skinner and Edge (2003) critically

reviewed the category systems for classifying ways of coping. They discuss the issues surrounding conceptualising and measuring coping and how this has slowed progress in the field of coping research. Over 100 category systems were examined by Skinner and Edge (2003), none of which included more than two of the same constructs of coping. The authors further discuss the inconsistencies with measurement scales and how coping categories were mostly formed out of the item being measured in a particular scale. The problem with defining clear categories for measuring coping is that coping is not a behaviour that can be explicitly observed or reliably reported (Hagger & Orbell,. 2021; Skinner & Edge., 2003).

Skinner and Edge discuss how coping can be seen as an "*organisational construct* used to encompass the myriad of actions individuals use to deal with stressful experiences"(pp.217). This statement suggests that coping should be seen as more of a combination of cognitive and behaviour attempts to process a stressful situation, regardless of whether these attempts reap positive or negative outcomes, this is still an attempt at coping. Coping should be demonstrated by these outcomes, whether someone is coping well would be demonstrated as their psychological and physical outcomes improving, a reduction in distress, and an improvement in daily functioning. This ideology can be seen in Hagger and Orbell's (2021) work on the extended model of stress and coping. As discussed earlier, they too propose that any action made towards dealing with a stressor is considered coping. This comes back to the classification of categories, as three of these were discussed above, table 2 shows a small sample of some of the other coping categories that have emerged from the coping literature over the last 20-30 years. Rather than considering how researchers measure these distinct categories of coping functions it should instead focus on coping as outcomes.

Table 2

Higher order distinctions among coping categories (Skinner & Edge, 2003)

Distinction	Definition	Source
Emotion-focused vs Problem-focused	Coping that is aimed at managing or altering the problem causing the distress vs. coping that is directed at regulating the emotional response	Lazarus & Folkman (1984)
Problem-Focused Coping vs Emotion-Focused Coping vs Appraisal-focused Coping	Dealing with the reality of the situation vs. handling emotions aroused by a situation vs. appraising and reappraising a situation involves attempts to define the meaning of a situation	Moos & Billings (1982)
Approach vs. Avoidance	Cognitive and emotional activity that is oriented either toward or away from threat	Roth & Cohen (1986)
Engagement vs. Disengagement	Responses that are oriented toward either the source of stress, or toward one's emotions and thoughts vs. responses that are oriented away from the stressor or one's emotions/thoughts	Compas et al., (2001)
Control vs. Escape	Proactive take-charge approach vs. staying clear of the person or situation or trying not to get concerned about it	Latack & Havlovic (1992)
Primary vs. Secondary vs. relinquishment of control	Efforts to influence objective events or conditions vs. efforts to maximize one's fit with the current situation vs. relinquishment of control	Rudolph et al., (1995)
Alloplastic vs. Autoplastic	Coping directed toward changing the environment vs. directed toward changing the self	Perrez & Reicherts (1992)
Volitional, effortful, controlled vs involuntary	Responses to stress that involve volition and conscious effort by the individual vs. responses that are automatized and not under conscious control	Compas et al.,(1997)
Behavioural vs. cognitive	Taking action or doing something" vs. mental strategies and self-talk	Latack & Havlovic (1992)
Social vs solitary	Utilise methods that involve other people or be done alone	Latack & Havlovic (1992)

Proactive	Efforts undertaken in advance of a potentially stressful event to prevent it or modify its form before it occurs	Aspinwall & Taylor (1997)

Whilst considering the issue of consensus on core categories and measuring coping as outcomes, this aligns with the aims of the work conducted within this thesis. The psychosocial toolkit can be considered as a consensus driven coping outcome focused measurement tool, using psychosocial health constructs as determinants for evidencing coping with a stressful situation such as cancer.

Most of the research on measuring coping has mostly focused on questionnaires and that the psychometric properties of a questionnaire are of crucial importance when choosing the appropriate measurement scales for research (Lundqvist & Ahlstrom, 2006). One of the most widely used instruments developed by Lazarus and Folkman (1988) is the Ways of Coping (WCQ) questionnaire, which was directly derived from their stress, coping and appraisal theory. The WCQ (Lazarus & Folkman, 1985; Lazarus et al., 1993) is a tool used to assess the coping style and effectiveness an individual employs when faced with a stressful situation. It assesses various coping strategies that ultimately only fit into problem-focused and emotion-focused coping. As discussed, these are not the only two coping styles that can be applied to a situation as the range of categories is vast (as seen in table 2).Therefore, only using a singular measure of coping would not be effective and so measuring outcomes may be more effective.

It is clear from the research presented that coping cannot be conceptualised in a unidimensional construct and therefore trying to measure coping is more complex. So far this thesis has presented an overview of the cancer policies spanning the last six years, the MRC framework that details how to develop and subsequently evaluate robust interventions and finally, the underpinning theory of how a person deals with stressful situations. The work conducted within this thesis is informed by all three of these elements and aims to address some of the issues surrounding coping whilst simultaneously achieving

the overall aims documented in this thesis. Given what has been discussed around self-assessment and coping, it is clear there is a need to explore how best to evidence how well an individual is coping with stress. Each of the cancer policies, detail the importance of PROMS, stakeholder engagement and building a consensus amongst people affected by cancer. By doing this, it would help to achieve the key objectives set out within the policies whilst also being informed by the core elements of the MRC framework, meaning the final result should be robust enough to help charities like Tenovus meet these key objectives. Identifying a core set of outcomes that have been informed by people affected by cancer is the best way of truly assessing how those individuals are coping.

The research above explains the various methods of coping that people engage with, and are effective, to help them adjust to their cancer diagnosis. This is where psychosocial interventions are relevant as they are designed based on the theories that help us understand these behaviours and aim to reduce the psychosocial impact of a cancer diagnosis and improve health outcomes. The following section will first review the types of psychosocial interventions that are typically offered and critically review the evidence for their effectiveness on improving psychosocial health outcomes. This is relevant for the research undertaken in this thesis as it is important to understand what is considered to be effective and how this is being evidenced.

Psychosocial interventions

There are a number of innovative psychosocial interventions delivered globally for people affected by cancer. This section will specifically focus on those that have been designed to improve the psychosocial health of people who have received a cancer diagnosis. Psychosocial interventions have been shown to be effective in improving key health outcomes such as quality of life, reducing emotional distress and improved social functioning (Gao, Tang, Li, Tan, Feng et al., 2013). Interventions can be individual, or group based and wide ranging in terms of content, mode of delivery, complexity and

intensity (Stanton, 2006; Weis, 2003) and are often facilitated by health professionals. Psychosocial interventions include a therapeutic dialogue between the patient group and the health professionals with a primary aim of improving key psychosocial health outcomes (Galway et al., 2012). The evidence base surrounding the efficacy of psychosocial interventions focuses on the four of the main categories: behavioural therapy; relaxation, biofeedback; educational therapy; coping skills and psychoeducation (Jenkins, 2010); psychotherapy; counselling and mindfulness and support groups which are often third sector or charity organised (Marks, Evans, Murry & Estacio, 2015).

Psychosocial cancer support includes a variety of effective strategies to help cancer patients and their families to emotionally adjust to all aspects of the cancer journey. This covers everything from diagnosis and treatment, treatment-related side effects, adherence to chemotherapy and improving overall health behaviours which impact quality of life (Penedo, Benedict & McGregor, 2013). Psycho-oncological interventions generally target key areas associated with the impact of cancer, these include emotional problems, assistance with social/practical problems, family and care giver support, spiritual aspects, improvement of general health condition, optimisation of treatment and physical symptoms (Lang-Rollin, Gotz & Berberich, 2018). The development and delivery of psychosocial interventions has become a detailed, skilled and organised activity guided by evidence (Watson, 2012). It is worth noting that not all patients will need, want or benefit from psychosocial support. However, the need for support is not always recognised by patients or clinical staff and can result in a mass of unmet needs, leading to longer term psychological consequences (Lang-Rollin, Gotz & Berberich, 2018).

Given the range of psychosocial interventions it is important to consider the evidence base for how they improve the lives of people affected by cancer. A systematic review by Teo et al., (2018) examined randomised control trials (RCTs) of psychosocial interventions for advanced cancer patients and concluded that the modalities involved in

psychosocial interventions can be grouped by their approaches. The approaches in the interventions reviewed in this paper included cognitive behavioural therapy (CBT), meaning enhancing (dignity, life review and narrative), counselling, education and music and writing (creative therapies). Sixty percent of the trials (n=20) examined were evaluated for their effectiveness and reported an improvement in quality of life as their primary outcome, and physical symptoms such as pain and fatigue. Studies that explored CBT based interventions compared to the usual care, found an improvement in patient's levels of self-efficacy and a change in attitudinal barriers.

There has been an increase in the number of Mobile health or mHealth interventions available to people and this modality became more relevant during the COVID-19 pandemic as people with cancer were at greater risk of complications if they were to contract the virus (Kuderere et al., 2020). MHealth or eHealth interventions can be delivered via mobile devices such as tablets, phones, apps and smart technology, usually requiring an internet connection. Bunevicine et al. (2021) conducted a systematic review and meta-analysis on mHealth interventions designed to improve Quality of Life (QoL) in cancer patients which overall provided support for improving at least one domain of quality of life. The 25 studies reviewed were grouped by the focus of the intervention which included physical activity/fitness (n=9), weight management (n=2), CBT (n=6), Mindfulness/stress management (n=3), social support(n=2), information(n=2), and pain management(n=1). Quality of life was evaluated in all the interventions in this review, with most studies using the European Organisation for Research and Treatment (EORTC;10 studies) and the Functional Assessment for Cancer Therapy (FACT; 7 studies) to measure the domains of quality of life. All of the studies reported improvements in at least one domain of QoL and provided evidence for the use of mHealth interventions in a cancer population, notably the overall results showed a statistically significant improvement in studies that measured QoL using the EORTC but not in those using the FACT-G. The

strongest evidence in this review highlights physical activity, CBT and mindfulness as the most effective in improving QoL in cancer patients. Despite the evidence for its efficacy, it is difficult to draw conclusions as to which specific type of mHealth intervention is the most effective from this review as there are an uneven number of studies in each subgroup and there have been concerns reported in the literature (Kumar et al., 2015) surrounding the lack of regulation of mHealth interventions in general, highlighting the development of the intervention and concerns over privacy.

An example of a UK based psychoeducation preventative intervention includes the 'Tenovus Health Check', an online intervention targeted at improving earlier symptom recognition and help seeking among hard to reach communities (Smits et al., 2016); interventions to improve treatment adherence include the provision of pharmacological and psychosocial support delivered via Mobile Units to break down geographical barriers to the provision of cancer care and support (Iredale, Hilgart & Hayward, 2011) which allow patients to access services outside the hospital setting, reduce travelling times and reach rural areas; and an eco-therapy based intervention which explored the therapeutic impact of engaging with an indoor nature-based coping intervention (Phelps, Butler, Cousins & Hughes, 2015).

Self-management interventions for cancer patients focuses on empowering people with the education and skills to enable them to cope better with the impact of cancer. Interventions that focus on self-management should include educating people about their disease, teaching coping skills and increasing their awareness of the support that is available to them. A recent systematic review by Cuthbert et al. (2022) examined self-management interventions for cancer survivors and found that interventions ranged from a single session to 12 months of sessions and were a variation of in person, (one-to-one and group) web, print or telephone based. Out of 41 interventions examined, less than half were based on a theoretical framework but most included components such as education

about their cancer and health behaviours and coping skills training which focused on coping with the psychological impact of cancer. The most commonly measured outcome was quality of life, evaluated in over half (n=26) of the interventions being examined and found that only 15 studies reported a statistically significant improvement, one with worsened quality of life and 10 were unchanged. They also found that outcomes such as anxiety, depression, distress, mood, fatigue and social support all had initial improvements but were not maintained at follow-up.

Effective psychosocial interventions are usually based on health behaviour change theories or stress and coping framework. As discussed in this chapter, Lazarus and Folkman's stress and coping model is widely used in the cancer field. A recent systematic review by Gabriel et al., (2019) identified 12 eligible intervention studies that aimed to improve quality of life in cancer patients and their family caregivers. The interventions reviewed highlighted that nine of the interventions (n=12) were based on Lazarus and Folkman's model of stress-appraisal, three were guided by cognitive behavioural therapy practices and three were guided by interpersonal theory. The interventions included methods such as health education, counselling, skills training, coping skills, goal setting, and reducing feelings of uncertainty. Quality of life (QoL) was the overall outcome being measured in each intervention which is a commonly and widely accepted outcome when evaluating the effectiveness of psychological and clinical treatment in the cancer field (Sibeoni et al., 2018). The review identified that QoL was evaluated using six different QoL specific tools and then a further battery of assessments that measured domains that make up quality of life. This review could not conclude the effectiveness of these interventions on improving QoL following an assessment of bias exploring the evaluation tools and methods used within each study. Similarly in a systematic review from Senchak et al., (2019) which looked at interventions designed to improve QoL in head and neck cancer patients, also measured QoL, but also anxiety, depression and PTSD using multiple

different assessment tools. The interventions identified in these systematic reviews are a good example of how multiple methods of measuring and evaluating quality life are used. This is a common occurrence when evaluating psychosocial cancer interventions where multiple assessment tools exist that claim to measure the same outcomes, but there is no clear gold standard measure making it difficult to compare outcomes across interventions. This can become a problem when trying to determine which interventions are the most effective, this is discussed further in [Chapter 3] when detailing the process of the systematic review undertaken for this PhD research.

It is clear that psychosocial interventions are effective in reducing [outcomes] related to a cancer diagnosis. The way in which the success or impact of interventions are evaluated does have issues, as discussed above, there are multiple different outcomes being measured and there is no clear set of outcome measures that are recommended because the cancer field is saturated with multiple assessment tools. Using the same assessment tools to measure the same outcomes across interventions would allow for a more systematic approach and an ability to draw comparisons across interventions. Many 'toolkits' exist but no universal idea of what to use and in the cancer field this gets very complicated with all the different types of cancers (explained further in chapter 4). There is clearly a need to be able to systematically evaluate the effectiveness of these interventions which the evidence tells us are needed to help people cope with cancer in order to know if they are best serving people with a cancer diagnosis. The long-term effect of this approach would allow service providers to know that the help they are providing is effective, highlight where there could be an unmet need in the population and ultimately this will strengthen the evidence base for delivering effective interventions.

In order to measure these key health outcomes, the use of Patient Reported Outcome Measures (PROMs) is needed. Patient reported outcome measures (PROMS) allow health status reports to be communicated directly from the patient and not interpreted

by a professional, exploring the psychosocial dimensions of the disease on individual health and functioning (Coulter et al., 2015). PROMS were first integrated into clinical trials to evaluate patient outcomes allowing clinicians to gain a better insight into the impact that a disease has on an individual's life and the complexity of experiencing illness (Jayakumar et al., 2017). When used in clinical settings they help to inform clinical care and decision making and predict long term outcomes (Calvert et al., 2014) and specifically in clinical oncology settings patients are more likely to report symptoms more frequently during their follow-up appointments (Takeuchi et al., 2011), facilitating effective communication and care planning with the clinician. However, Calvert et al., (2014) discusses that although the use of PROs is highly beneficial, the data collected can be easily undermined by the amount of missing data within a given evaluation period. The questions asked and domains measured within PROMs are subject to interpretation by the individual and can often lead to the variation in outcomes and missing data.

Cancer and COVID-19

Given the already identified psychosocial challenges that come with a diagnosis of cancer, the additional all too prevalent threat presented by the COVID-19 pandemic that emerged in March 2020 (and the beginning and duration of the 3rd year of this PhD) presented additional clinical and psychological concerns for an already highly vulnerable population. The following will discuss the impact of COVID-19 on the cancer pathway during this time, however the long-term impact is not yet known.

The COVID-19 lockdown measures had a dramatic impact on cancer care. Routine screening, some treatments and support were all suspended during the early months of the pandemic (Blood Cancer UK, 2020). The full impact of COVID-19 on people affected by cancer is now becoming clear, with a lack of screening, urgent referrals, surgeries and treatments being halted or delayed during the pandemic, it is predicted that there will be a severe long-term impact (CRUK, 2020). Some of that impact can be seen in the reduction of

new cancer diagnosis, specifically in breast, bowel and lung. The DATA-CAN (Cancer Collaboration Cymru) research group analysed data from NHS Wales which reports that there was a 15% reduction in new cancer diagnosis in 2020 compared to 2019, especially those which are screening related (breast and bowel) as these were paused between March 2020 and July 2020 (Data-CAN, 2022). The greatest impact was seen in breast cancer screening related diagnosis which reduced by 48%, compared to bowel at 13%. However, it is important to note that bowel cancer screening takes place at home so this would explain why breast cancer screening had the bigger reduction (Green et al., 2022; DATA-CAN, 2022).

During the pandemic, individuals with cancer who had received specific cancer treatments were believed to have an increased susceptibility of contracting and suffering great consequences of covid-19 (Guan et al., 2019; Liang et al., 2020; UKCCMP, 2020). In order to manage this risk, the government guidelines from March 2020 for people with cancer, or who have undergone specific cancer treatment, were advised to undertake shielding measures during the covid-19 pandemic whereby they were not to leave their houses at all and avoid contact with other people in order to lower their risk of contracting the virus. (UKGov, 2020; NHS England, 2020). The NHS aimed to continue essential and urgent cancer treatments during this period, which were treated on a case-by-case basis depending on levels of vulnerability. The creation of 'cancer hubs' were implemented in London, creating a safer space away from the hospital environment to allow the safe delivery of cancer treatment (Tenovus, 2020; UKGov 2020) however there was nothing similar implemented in Wales. In 2020 it was estimated that only around one quarter of urgent referrals were being dealt with in Wales (BBC, 2020) and DATA-CAN (2022) report that urgent referrals for suspected cancer through the GP decreased the most for lung and bowel cancer during the pandemic.

Evidence from similar situations (SARS-CoV 2003 outbreak) predicted that there will be a global impact on mental health with increased levels of stress, anxiety and depression amongst the population as a whole (Torales et al., 2020). As well as potentially experiencing an increase in levels of isolation and loneliness due to the lockdown restrictions, individuals with cancer also fell into the "vulnerable" group as described by the WHO and central government that also required them to follow shielding advice. As well as having to manage the amount of information being communicated daily which may be overwhelming and stress-inducing for some individuals (Anxiety UK), individuals with cancer also had to understand and accept the current changes to their clinical care with all the anxiety and confusion that may cause (CRUK, 2020). Advice from Ovarian Cancer Action (OCA, 2020) during the early stages of the pandemic recommended that should individuals find that they are becoming overwhelmed with the information they are being communicated daily they should; limit the time spent looking at covid-19 related information and when they do engage they should ensure they are accessing information from credible sources; engage in some self-care activities such as meditation, yoga, and plentiful sleep; and stay connected with friends and family through virtual means.

The COVID-19 pandemic was an unexpected event that significantly impacted the cancer population in Wales. It is important to highlight the role of the pandemic and how it relates to, and impacted the research undertaken within this thesis. The pandemic prevented cancer support services from running normally which included the services provided by charities like Tenovus Cancer Care. This of course meant that not only did they have to pause their support services, but they also had to place a significant number of staff on furlough. The evidence already depicts the impact of receiving, or living with, a cancer diagnosis in addition to the stress caused by waiting for results, treatment, or support. It is important to be able to constantly assess and review the support that is being provided to ensure it always meets the needs of the population as best as possible. Data

showing the impact of covid-19 on individuals with cancer is only now starting to become clear as there was no infrastructure in place to assess and adapt to the situation and best support people with cancer. The country now faces a backlog from the pandemic which is an increasing number of people waiting for cancer diagnosis, treatments and support. A statement from the Welsh Government in July 2022 reported that they saw a 16.7% rise in referrals in May 2022, compared only to April 2022 and they claim to have reduced the longest waiting times (two years) by 4.4% after two years of consistent rises (Welsh Gov, 2022). The research undertaken in this thesis was adapted to fit the current climate but ultimately provides a protocol for being able to evaluate the psychosocial impact of any psychosocial intervention on an individual with cancer and that is particularly relevant given the impact of the pandemic.

Chapter Three: Methodology

This chapter will explore the philosophical research paradigm used for this research and provide an overview and justification for the methods employed for each inquiry. To recap, the overall aims of this research were:

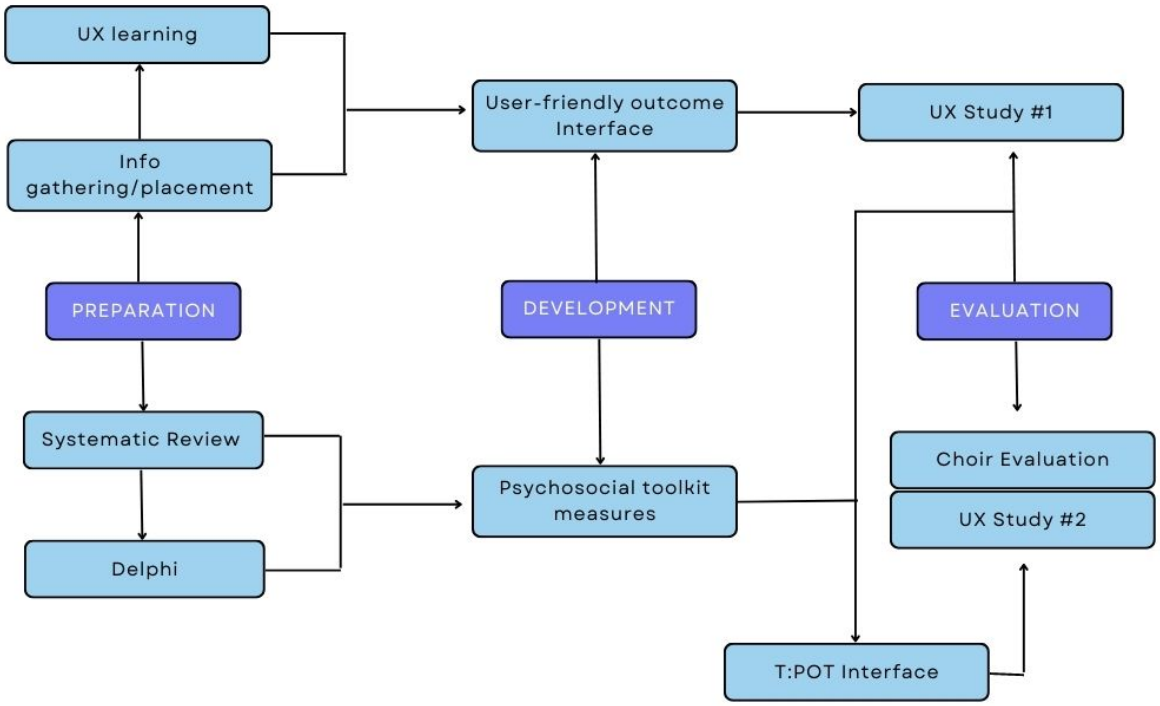
1. to identify, quantify and map core evaluation outcomes for psychosocial cancer initiatives and secondly,
2. to develop and evaluate the utility of a bespoke computer database offering a user-friendly interface that does not require specialist knowledge or skills to navigate.

As is clear from the aims above, this thesis entailed a mix of applied research and practical development due to the nature of the KESS2 studentship aims discussed in chapter 1. By the end of this chapter, it should be clear what approach was taken, why the methods were used and how they all fit together to form the final product and live evaluation.

This thesis represents a multi-phased mixed methods approach to the research enquiry, with the initial phase involving an in-depth systematic review of the existing empirical literature, the second phase involving engagement with key stakeholders in the co-production of an identified set of outcome measures and preferred design interface, and the final phase involving the design, creation and subsequent qualitative and quantitative evaluation of the final toolkit and interface. Figure 5 depicts the overarching connections between each phase and data collection process. The entire thesis and data within it can be viewed as a preparation, development, and evaluation phase. This corresponds to the pragmatic approach that will be explored in this chapter in more detail and aligns with some of the models put forward for mixed method research.

Figure 5

An overview of how the research links together



Pragmatic research paradigm

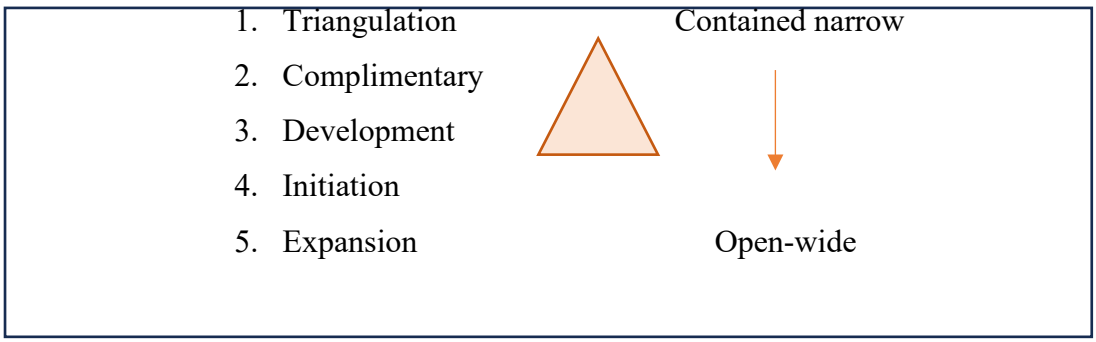
Prag-mat-ic = dealing with things sensibly and realistically in a way that is based on practical rather than theoretical considerations.

The pragmatic research paradigm advocates for using multiple methods of inquiry that are based on the best choice for the research question (Onwuegbuzie & Leech, 2005) with the philosophy that the research question should drive the methods used. Pragmatism draws from the interpretivist and positivist assumptions by accepting that reality is constructed by individuals but at the same time accepting that it is a reconstruction of something stable that already exists. Pragmatic researchers will use both traditionally qualitative and quantitative methods, however an interesting reframing discussion from Onwuegbuzie and Leech (2005) suggests that researchers should instead use the terms ‘exploratory’ and ‘confirmatory’ methods to bring them under the same framework rather

than viewing them as two separate entities. There is quite a divide amongst qualitative and quantitative researchers with people often finding themselves in one 'camp' but as a pragmatic researcher, the use of all methods or the best methods available for answering the research question seems to make the most sense. Pragmatic researchers promote more flexible investigative techniques and collaboration. A framework proposed by Greene, Caracelli and Graham (1989) describes five broad purposes of mixed methods research.

Figure 7

Green et al. (1989) Mixed methods framework



Within this framework by Green et al. (1989) triangulation describes a very narrow method of enquiry, gradually working through the principles to become a more open and objective method of enquiry. Noble and Heale (2019) describe how using triangulation in research refers to the blending of the results of multiple methods in an attempt to increase the reliability and credibility of the findings. Triangulation is the best fit to describe the approach taken within this thesis. An example of this is how the results of the systematic review were blended with the results of the Delphi study to develop the psychosocial toolkit. In regard to reliability and credibility, one of the main objectives of the systematic review was to examine the methodological quality (reliability & validity) of the instruments identified to increase the credibility of the final toolkit.

The further four steps of the model proposed by Green et al. (1989) - complimentary, development and expansion also help to explain the methods used within

this thesis. The purpose and rationale of each of these purposes and how they apply to this research at various stages are as follows:

Complimentary – seeks elaboration, enhancement, and clarification of the results from one method with the results of another. Aims to increase the meaningfulness and validity of the research.

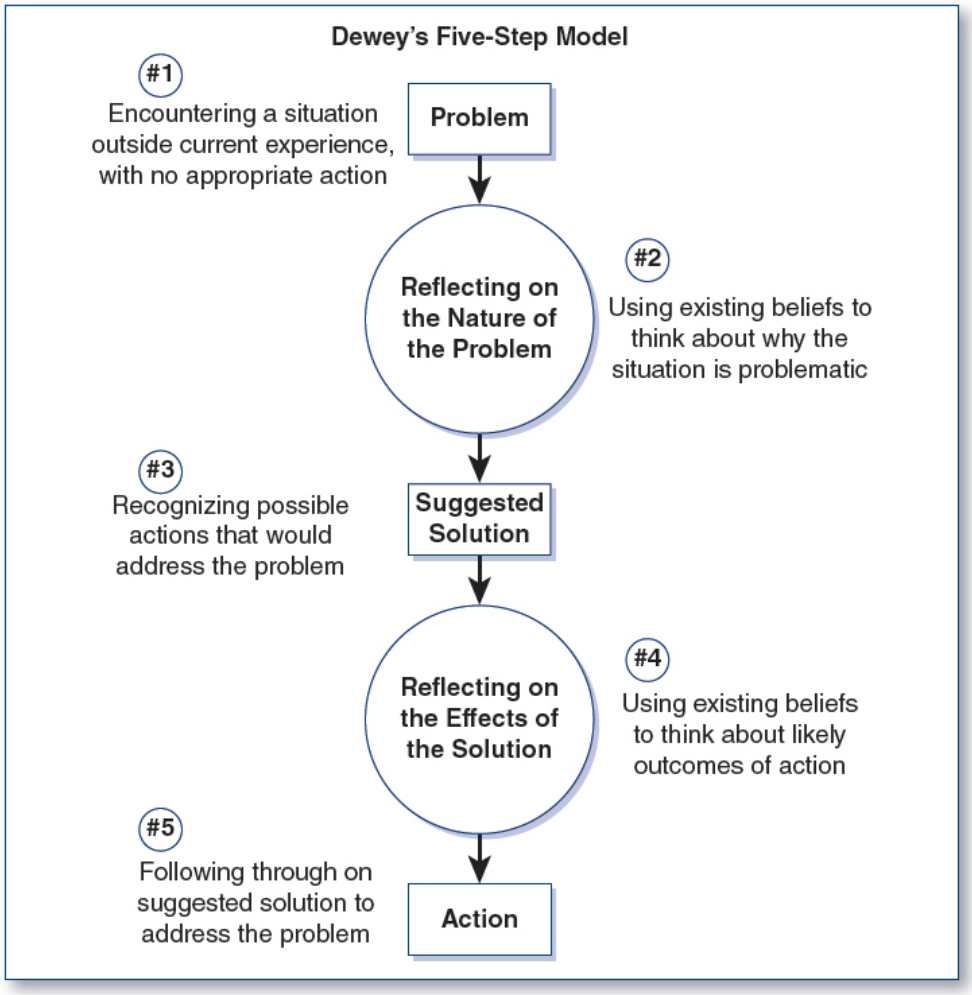
Development – seeks to use the results of one method to inform another method, including measurement decisions. Aims to increase the validity of the research by capitalising on the method strengths.

Expansion – seeks to extend the breadth and range of the research enquiry by using different methods for the various components of inquiry. Aims to increase the scope of inquiry by selecting the most appropriate methods for perusing the inquiry.

These principles together help to explain the methodological choices within this thesis. The research begins with a systematic review and methodological quality examination of patient reported outcome measures validated on a cancer population. The primary aim of the systematic review was to examine what already existed within the field of psychosocial cancer evaluation and to critically evaluate its methodological quality. The outcome of this review directly informed (*complimentary)* the second study employing the Delphi consensus technique (*development)* which together helped to develop the psychosocial evaluation toolkit.

Figure 8

Dewey's Five Step Model



Dewey's (1933; Morgan, 2014) five step model for understanding problem solving best represents the pragmatic approach taken to the research methods contained within this thesis. In step four, the process of reflection can often lead a researcher back to step one, to rethink the methods proposed to address the research question, based on constantly acquiring new knowledge. The researcher is not only guided by their own beliefs, the shared beliefs of the research community, and personal experiences, but they also learn from the experiences of others, which all contribute to this process of reflection, reassessment and then action (Morgan, 2014). How this applies to the current research is explained below.

Step #1: Problem

Prior to the inception of this PhD, the researcher worked on multiple funded research projects with Tenovus Cancer Care which all had the aim of evaluating the psychosocial impact of their cancer support services. Throughout the process of deciding upon evaluation outcome measures, it became apparent that there is an abundance of psychosocial measures to choose from, each measuring different health outcomes. The process of deciding which measures would be the 'best' to choose was unclear as there is no standardised guidance to follow. The researchers previous experience of this process usually relied on an unstructured review of the literature, exploring the reliability and validity of the measures at best. Following this the decisions would be made amongst the research team by pooling together the shared experience to make a judgement. The purpose therefore for this PhD research was to develop a more strategic and meaningful way of choosing the 'best' outcome measures when conducting a psychosocial evaluation of cancer support services. The hope is that this would create a more seamless approach to evaluating impact. As part of the KESS partnership with Tenovus Cancer Care, a number of placement hours had to be completed throughout the three-year period. This was essential especially at the beginning of the research in order to establish the needs of Tenovus and formed a huge part of the preparation phase of this research by allowing the researcher to become immersed into the charities research team and understand more about how and why they wanted to evidence the impact of their services.

Step #2: Reflecting on the nature of the problem

When observing that each evaluation conducted was being assessed on different outcomes each time, it was noted that the Tenovus research team had no way of directly comparing their services against each other which would directly inform how their services were performing. This became a problem as they were struggling to evidence the impact of

their services regularly without outsourcing to a university research team each time. This is a time consuming and expensive process for a charity to engage with each time.

Step #3: Suggested solution

The suggested solution to this problem is reflected in the aims and objectives of this research. To develop a way in which Tenovus could evaluate their services using the same outcomes which would allow them to directly compare services against each other. To do this the researcher first had to consider which outcome measures would be the best choice to achieve the most comprehensive psychosocial evaluation. Secondly then to create a system that would allow Tenovus to easily conduct these evaluations, and that would display the outcomes in an easy-to-read manner. This would mean that any member of staff at Tenovus could look at the system and know the most recent results for that service.

Step #4: Reflecting on the effects of the solution

It is expected that the proposed solution of developing a psychosocial toolkit and computer interface that would allow Tenovus Cancer Care to systematically evaluate and compare their services across the same psychosocial health outcomes would provide valuable insight and information and would be time and cost effective. This work undertaken in this thesis aimed to combine applied psychology with applied computing and create a solution for a charity who were in need of something reliable and credible to not only evidence the psychosocial impact of their services but for it to be accessible to their staff without specialist training.

Step #5: Action

The action stage of Dewey's model represents what was actually done to address the problem and whether the proposed solution was achieved. The entirety of this thesis is a walkthrough and reporting of the action stage. However, what is not fully reflected is the circling back through the steps when a new problem arose, there is reference to the

COVID-19 pandemic throughout but the full reality of navigating through the pandemic as a researcher is not fully reported. By the end of 2021 a final action plan was reached that would allow the proposed solution to be achieved.

The methodological enquiry

There is a vast amount of psychological literature, some of which has been discussed in the previous chapters, detailing the psychosocial impact of a cancer diagnosis, living with cancer, treatment and beyond. What is known already, is that cancer can have a detrimental effect on an individual's mental health and wellbeing, and that most individuals benefit from some variation of psychosocial support. What is also known, is that the psychosocial support interventions are the most successful when they have been developed effectively and are evaluated regularly and rigorously. Methods of psychosocial evaluation rely heavily on self-reporting measurement scales which has been critiqued for being ambiguous because of the reliance on self-evaluation of a person's own psychological characteristics, behaviour and bodily changes. Highly scientific psychologists do not believe that self-report measures can be relied on as accurate enough to be called science Although this must be acknowledged, there is much support for self-reporting to be the most representative of that person's experience, and effort should be made instead to increase the validity, reliability and overall quality of the measurement scale (Lazarus, 1999). This ideology of strengthening the scientific value of self-report measurement scales mixed with the pragmatic worldview that no two individuals will have identical experiences but the shared experiences between those people can lead to shared beliefs (Morgan, 2014). This is especially relevant for this thesis because no two people with cancer (even if it is the same diagnosis) will have identical experiences but they will share the experience to a huge degree. This is important to remember when designing and evaluating interventions, to design something to improve the shared experience of people with cancer.

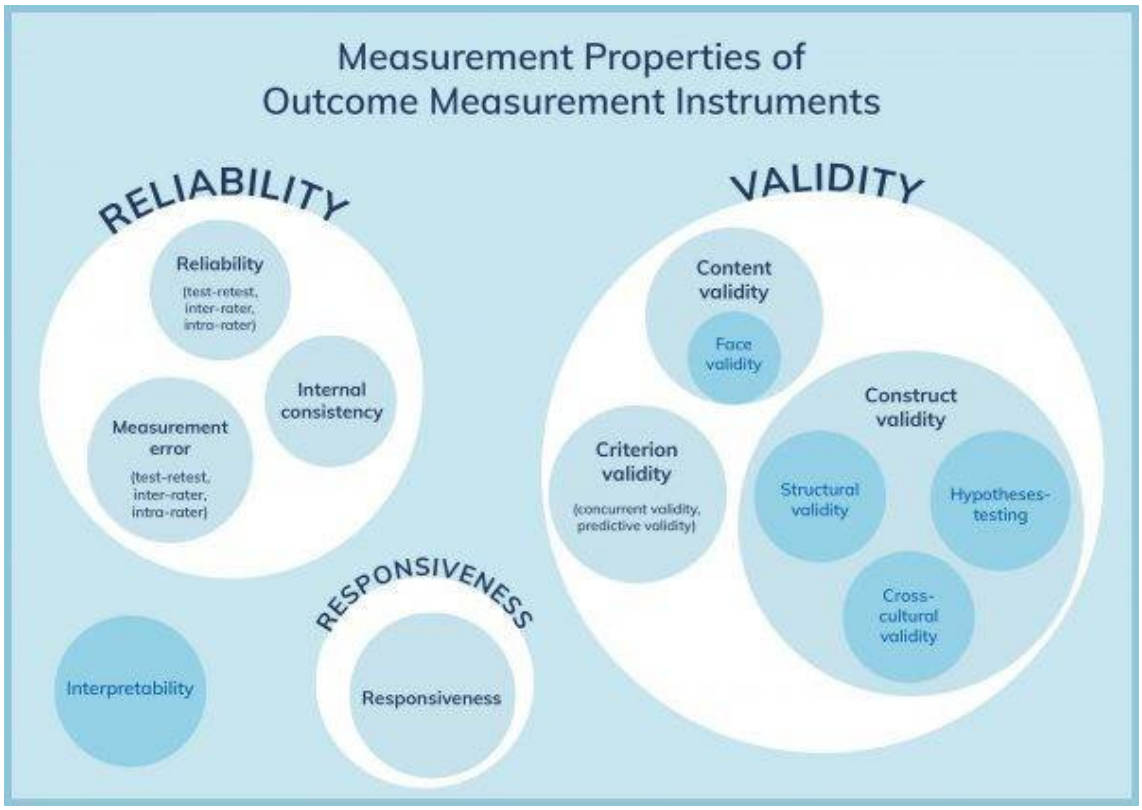
Study one

One of the main aims of this research was to develop a psychosocial evaluation protocol to evaluate the relative impact of a cancer support service. To do that the research had to first begin with a systematic review to find all the patient reported outcome measures (PROMS) designed to evaluate the psychosocial health of cancer patients. This step was important not only to systematically search for, and decide on a set of psychometrically strong outcome measures but also to form part of the first step of planning a Delphi study. As will be discussed further, the second phase of this research involved a Delphi consensus building technique and the first step of conducting a Delphi study includes a systematic review (Boulkedid et al., 2011). The systematic review protocol (discussed further in chapter four) was designed to locate all of the validated questionnaires that explored aspects of psychosocial health that were specifically designed for use on people with a cancer diagnosis. The second aim of the systematic review was to examine the methodological quality of the outcome measures that had been identified in the systematic review. Examining methodological quality is important because there are a vast number of PROMS to select from which makes it difficult to decide which is the most appropriate and which will produce the most accurate outcomes, and involves assessing the psychometric properties of the scale (Mokkink et al., 2021).

The initial development of a PROM should also be of a good standard, meaning that it should be a reliable tool with clear constructs to be measured, responsive to change in condition and validated on the proposed target audience (Rosenkoetter & Tate, 2017). There is an increasing focus on co-production with patients, consumers and professionals during the development of a measurement instrument to establish higher quality outcomes (Wilson, 2018). One method of assessing the level of quality within an instrument is by using the Consensus-based standards for the selection of health measurement instruments (COSMIN; Mokkink, Prinsen, Patrick, Alonso, Bouter, de Vet & Terwee, 2018).

Figure 9

COSMIN measurement properties of outcome measurement instruments diagram



The Consensus-based Standards for selection of health Measurement Instruments (COSMIN; Prinsen et al., 2016; Mokkink et al., 2010) checklist was used to assess the methodological quality of the outcome measures by examining nine measurement properties each with their own quality criteria, making up three main domains. Figure 9 depicts the three overarching domains which are 'Reliability', 'Validity' and 'Responsiveness'. Within the reliability domain is reliability, measurement error and internal consistency; within the validity domain is content validity and face validity, criterion validity, construct validity and structural validity, hypothesis testing and cross-cultural validity. The COSMIN checklist is set up with a predetermined excel spreadsheet which allows you to explore each of these measurement properties for every validated scale being examined. The excel checklist consists of nine boxes (each measurement property) with 5-18 items within each box that describe the questions to ask or the standards that should be met when evaluating that measurement property and determining the quality. Each of the items within the box for the corresponding measurement property

is rated on a four-point scale; very good, adequate, doubtful and inadequate. The overall score for the measurement property was determined on a 'worst score counts' method, meaning one lower scored item would bring down the overall rating of the measurement property. The methodological quality of a study was determined per measurement property. This then allows each scale to have a profile of measurement properties that have been evaluated for methodological quality and a decision can be made about the scale overall.

For this research, the quality of the overall scale needed to be quantified to be able to rank them in order of quality from better to worse. To do this a value was assigned to each point on the rating scale e.g., very good = 4, adequate = 3, doubtful = 2, inadequate = 1 and where there was a value missing it was assigned a zero. The information required in order to assess each measurement property of a given scale was acquired from the published peer reviewed journal article reporting its development and validation.

The COSMIN process allows outcome measures to be evaluated according to their methodological quality. Other critical appraisal tools are available such as Evaluating the Measurement of Patient-Reported Outcomes (EMPRO, Valderas et al., 2008) and Scientific Advisory Committee of the Medical Outcomes Trust (SACMOT, 2002). COSMIN was chosen as it is the most up to date critical appraisal tool which has been developed following the use of other tools and finding flaws within those tools. The SACMOT aimed to develop a set of attributes that would provide criteria for a measurement instrument to be designed and carried out. However, these attributes were not based on a psychometric framework and did not include any individual items or scoring system, therefore this was used as the basis for many other tools e.g., the EMPRO. The EMPRO was developed to standardise the assessment of patient-reported outcomes, the 39-item guidance was designed based on the SACMOT measuring the same eight domains with the addition of a four-point scoring system. The COSMIN checklist was chosen as it

has been developed to specifically assess more domains that make up methodological quality than the previous tools (Rosenkoetter & Tate, 2017).

The following explains the role of each measurement property within the COSMIN checklist and how it is relevant to the quality of a PROM (Frost et al., 2007; Prinsen et al., 2016; Mokkink et al., 2010). Each of these were used to guide the methodological evaluation of each PROM identified in the systematic review reported in Chapter four.

Reliability is defined as the extent to which scores for patients where their disease status has remained unchanged, produce the same scores when the scale has been repeated on a different occasion. For example, using different sets of items from the same questionnaire (internal consistency), over time (test-retest); by different people on the same occasion (inter-rater), or by the same people on different occasions (intra-rater). As per the COSMIN standards, reliability is assessed by examining internal consistency, measurement error and reliability. Typically, reliability will increase with a greater number of items being measured. However, with a greater length of questionnaire comes the consequence of increased response burden.

Internal consistency of a scale defines how correlated the items are within the questionnaire and is expressed by a Cronbach's α or Kuder-Richardson Formula 20 (KR-20). If a scale has subscales, they should have a value calculated for each one to show the reliability of that subscale.

- ***Measurement error*** is the systematic and random error of a patient's score that is not attributed to true changes. This is examined by the standard error of measurement (SEM). Measurement error is concerned with small changes in scores which are not attributed to true changes.
- ***Reliability –*** unlike measurement error, reliability is concerned with the changes that can be attributed to true differences between patients. This is

expressed by calculating the intraclass correlation coefficient (ICC) or Cohen's Kappa.

Validity is the extent to which a questionnaire is measuring exactly what it has set out to measure. Validity is made up of the following subtypes that are evaluated individually:

- ***Content validity*** is concerned with the content within a questionnaire and whether this is an accurate reflection of the construct being measured. It examines whether all the items within the construct are relevant to the aim and target population and that no crucial items are missing.
- ***Criterion validity*** refers to the comparison to a gold standard questionnaire, however it is difficult to evaluate due to a lack of gold standard health status questionnaires. For the purpose of this review, following the COSMIN guidelines, if a questionnaire was a shortened version, then the gold standard became the original full item questionnaire.
- ***Construct validity*** is usually examined by correlations, factor analysis and multivariate regression models. the COSMIN checklist examines construct validity across three subtypes: Structural validity, hypothesis testing and cross-cultural validity.
- ***Structural validity*** is usually determined by factor analysis to assess the constructs within the questionnaire. A factor analysis confirms whether the scores of the questionnaire are an adequate reflection of the dimensionality of the construct to be measured. Factor analysis also allows confirmation of the number of constructs within a questionnaire. There are times when constructs work better combined or need to be split up so achieve better representation.

Hypothesis testing is concerned with how the measure relates to other measures in regard to the construct it claims to be measuring. A pre-defined hypothesis would expect certain measures to interact or complement each other.

- ***Cross-cultural validity*** is measured by examining the performance of the questionnaire items when they are translated or culturally adapted. For the purposes of this review, cross-cultural validity was not a focal point for measuring quality however it is evaluated if the reporting paper documents it.

Responsiveness of a questionnaire is the ability to detect change over time within the constructs being measured. It is considered to represent validity when used in a longitudinal context as this is how it would best show changes and is usually examined by looking at the correlation between the changes in scores and if they are in accordance with pre-defined hypotheses.

- ***Interpretability*** is the ability to be able to attribute qualitative meaning to quantitative scores. This allows for clinically significant meanings to be explained and especially relevant in a health status context. Interpretability allows for greater meaning to be given to patient scores. Although interpretability is not a measurement property, it is considered an essential characteristic of a measurement instrument.

Study two: An online modified Delphi study exploring consensus on key psychosocial outcomes for cancer populations

The second empirical study conducted within this thesis employed the Delphi technique to explore consensus on key health outcomes identified in the systematic review. The purpose of the Delphi was to engage with a range of cancer experts to explore their opinions on what key health constructs are important and relevant to measure in a psychosocial evaluation. This study employed a two-round Delphi with the systematic review acting as the information building prior to the expert consensus rating taking place. The following discusses the history of the Delphi technique and why it was chosen for this research, the full study is reported in Chapter 5.

The Delphi technique was originally developed by the RAND Corporation in the 1950s. The RAND Corporation are a non-profit organisation who help to improve policy and decision making through research and analysis ("A Brief History of RAND", 2019). The Delphi technique is a consensus building method using a series of questionnaires and controlled feedback (Dalkey & Helmer, 1963; Day & Bobeva, 2005). The technique requires the use of pre-defined 'experts' within a particular field, to pool together their knowledge to reach a convergence opinion on real world subjects (Baines & Regan de Bere, 2012; Goodman, 2016). The Delphi method is becoming more frequently used within Participatory Action Research (PAR), in PAR participants are viewed as research collaborators who possess the knowledge and agency to contribute to the design and collection of the evidence. Using the Delphi technique within PAR allows the properties of PAR to be honoured (participants involved at each stage and change-orientated research) whilst maintaining confidentiality amongst participants (Fletcher & Marchildon, 2014). The Delphi technique is most commonly used in health research and policy consultations (Boulkedid et al., 2011), with a growing focus on patient and public involvement within research design and data collection (Williamson, Young, Bagley & Gamble et al., 2017).

There are four key elements that inform the design and delivery of the Delphi technique. These elements are described in detail below (Skulmoski, Hartman & Krahn, 2007):

- *Anonymity amongst participants*: this allows for free expression of opinions without pressure from the other group members and prevents group domination. However, some research suggests that it reduces participant accountability and may encourage snap decisions (Fletcher & Marchildon, 2014).
- *Multistage iteration and controlled feedback*: this allows participants to review their answers in comparison to the group summary, controlled feedback informs the

participants of the group response as a whole and can offer the option to clarify their responses.

- *Statistical aggregation of group response*: this allows for quantitative analysis of the data, often looking at mean ratings, stability of responses between rounds and percentage of consensus between participants.

It is frequently documented in the Delphi literature about the lack of consistency when conducting or reporting a study which uses the Delphi technique. A systematic review by Boulkedid et al. (2011) explored the use of the Delphi method when determining performance indicators in healthcare. They concluded that there is a large variation in the way that studies using this method of consultation are reported, with many lacking in detail about response rates, feedback processes and the final results following consensus (in this case, the finalised performance indicators). A later review by Diamond, Grant, Feldman, Pencharz and Ling et al. (2014) also supported this by finding that there was still variation in the reporting of Delphi studies, more specifically about what defines consensus and how some studies used reaching consensus to signify the end of the study and others used a pre-defined number of questionnaire rounds. Both reviews and further research into this issue (Hasson, Keeney & McKenna, 2000; Boulkedid et al., 2011; Davidson, 2013; Diamond et al., 2014) concluded that there is a need for clearer guidelines for the conducting and reporting of Delphi studies and encourage researchers to document the in-depth process they undertake when using this method in their research.

Despite the lack of clear guidelines for employing the Delphi technique, there are assumptions as to what defines the reliable use of the Delphi technique which includes anonymity of panel members, multistage iteration and controlled feedback, and group response (Snape, Kirkham and Preston et al., 2014). The subject of anonymity was heavily criticised during Dalkey and Helmer's (1963;1967) original work as the 'expert' panel

members met face-to-face and were known to each other as they had previously worked together on other research projects (Davidson, 2013). The development of the Delphi method being conducted more rigorously lead to researchers modifying the original structure which is often reported in the literature as a modified Delphi (Khodyakov et al., 2016; Kearney et al., 2017). A modified Delphi is further described by Davidson (2013) to include online iterations, groups that focus on policy and electronic decision aids (handheld devices). Most importantly there is a crossover within the definitions of all of these adaptions to the method, therefore all meet the criteria for a reliable modified Delphi technique. The most common modification to the Delphi technique is online delivery. This is referred to as an *Online Modified Delphi* (OMD; Khodyakov et al., 2016) or e-Delphi, where the same stages of iteration and feedback are followed but it is administered online so as to ensure anonymity amongst group members. There are other methods of exploring consensus available, such as *Nominal Group Technique* (NGT; Delbecq & Van de Ven, 1975) however they all required participants to meet face-to face. The advantages of using an OMD include being able to reach a diverse range of people, it is cost effective and time saving as there is no need to travel, individual responses are not influenced by potential dominating group members and all feedback is anonymised (Fink, Kosecoff, Chassin & Brook, 1984; O'Neill et al., 2018).

Kearney et al., (2017) utilised a modified Delphi which included two online survey rounds and a stakeholder consensus meeting. Expert panel members were given a unique identifier to ensure anonymity and were asked to rate items for importance on a scale of low to critical importance. This continued until they reached consensus on the most critically important items. Through this process they identified which topics should take priority when conducting research with patients in clinical trials, a consensus was reached when at least 70% of panel members had agreed on their level of importance. Additional recommendations regarding the number of questionnaire rounds are provided by Black et

al. (1999; O'Neill et al., 2018) which suggests that the optimal number of questionnaire rounds should be between two and three. This is enough to generate convergence of opinions amongst individuals without having an adverse effect on response rate, as this is likely to happen if there are more than three rounds.

Using the Delphi technique allowed for a good way of involving patients and the general public (PPI) in the research. Cancer Research UK (CRUK) designed a PPI toolkit for researchers which explains that using PPI can improve the quality and relevance of the research being carried out, by involving those who can benefit the most from the research and ensuring the outcomes better reflect their needs. Involving patients in the whole process from planning to dissemination benefits the researcher and the patient population in question. Benefits include the relevance of results, quality of data collected, greater impact, and better recruitment and retention during data collection. The Wales Cancer Research Centre (2017) also supports the use of PPI and promotes it as an active partnership that works together to improve the health and wellbeing of individuals with cancer. It is good practice to involve the target population in the development of any new outcome measure, the aim here was not to develop a new measure but to help make decisions about which health constructs within these validated scales are the most important and relevant to that target population. The hope is that it would avoid any unnecessary questioning, allow outcomes to be generalised and comparable across different services, provide a more streamlined approach to intervention evaluation, and overall, better reflect the cancer population when evaluating the impact of a support intervention.

The field of human-computer interaction

As part of the aims of this PhD, a computer interface was designed to house the psychosocial toolkit that was developed. For the researcher this meant learning new skills in the field of human-computer interaction, user experience design and database

development in order to best meet these aims. The human-computer interaction (HCI) field is an area of applied computing that focuses on the relationship and interaction behaviour between a human and a computer system (Kaufmann, 2012). The user experience design (UXD) process is one of the ways in which this HCI is explored and evaluated. The Interaction Design Foundation (2014) discusses the purpose of user experience design and how it concerns itself with four main elements relating to usability, adaptability, desirability and providing value to users. Usability refers to how useable a product is, which is very dependent on what the purpose of the product is and how it is being used (Jeffrey, 2008). It is important to examine a user's interaction with a product such as a website or interface as early in the design process as possible. This allows for greater reduction in error in the final product. This is the process that was followed for this study in the development and evaluation phase. The user experience evaluation of the T:POT interface was split into a heuristic evaluation with applied computing experts and two usability evaluations. The methods involved within these studies are reported in more detail in Chapter 6, however they included the use of the Think Aloud method and user experience and usability questionnaires. This allowed for both quantitative and qualitative data to be collected and subsequently feedback to the developers of the interface for changes to be made.

The pragmatic approach to the research contained within this thesis means that a broad range of methodologies have been incorporated and triangulated for the best results. The remainder of the thesis reports on the empirical studies and interface development process that were both then triangulated for the final outcome.

Chapter Four: A systematic review examining the methodological quality of existing psychosocial patient reported outcome measures (PROMs) validated on a general cancer population.

Cancer has become one of the leading causes of morbidity and mortality worldwide (WHO, 2018) with the most up to date cancer statistics reporting over 375 thousand cases of cancer in the UK every year (CRUK, 2020). Cancer charity Macmillan, state there are 3 million people living with cancer in the UK alone and it is expected that this will rise to around 3.5 million by 2025 and 4 million by 2030 (Macmillan, 2021). Evidence clearly indicates that cancer has a significant impact on an individual's psychosocial health and quality of life, affecting their mental, emotional, social and spiritual well-being (Adler, 2008; Ogden, 2012). The most commonly cited factors affecting individuals with cancer are found to be depression and anxiety (10% of the cancer population) compared to 5% and 7% of the general population respectively (Pitman et al., 2018). Although anxiety and depression are the most common factors associated with the impact of cancer, they are often neglected or left undiagnosed (Milligan et al., 2018; Pitman et al., 2018), leading to adverse outcomes such as poorer quality of life and survival (Andersen et al., 2014).

With the advancement in cancer research, individuals are being diagnosed earlier and treatments are becoming more effective, resulting in more people surviving or 'living well' with cancer **(**Tracey et al., 2010; Arantzamendi et al., 2018). Accordingly, the need to ensure the availability of effective and appropriate psychosocial support and interventions within the cancer population is becoming more urgent than ever (Shouten et al., 2016). Measuring health outcomes in scientific research plays a crucial role in decision making regarding future treatments and allows the impact on health status to be evidenced (Mokkink et al., 2010). It is important for those who provide care and support for individuals affected by cancer, especially psychosocial support (NHS, third sector, and charity) to be confident that they are able to deliver cost-effective evidence-based interventions. Measuring the impact and improvement in health status can be complex and

widely variable (Nolte et al., 2013), this becomes problematic for service providers when they want to establish where best to direct their research funding, demonstrate the efficacy of their interventions and ultimately achieve the best outcomes for service users (Fish et al., 2017; Wilson, 2018). Research by Adler (2008); Grassi et al., (2016) and Wilson (2016) support the notion that there is a need to identify the most psychometrically robust way of allowing key health outcomes to be collected, logged and mapped systematically in order to provide the most effective evidence.

In order to achieve the objective of measuring key health outcomes, this is done through the use of Patient Reported Outcome Measures (PROMs). The notion of PROMS was introduced in Chapter 2 but are directly relevant to the systematic review. PROMS allow the collection of self-reported health related data to be captured from the individual's perspective versus the clinician's perspective. Having been first introduced in clinical trials (Jayakumar et al., 2017) they now provide a valuable insight into evidencing the impact of psychosocial interventions. The problem arises when it comes to choosing the appropriate PROMS and which health outcomes to measure. There is an abundance of PROMS available to measure the same outcomes and this becomes difficult when trying to draw comparisons between interventions or, knowing which measures are the most reliable and credible if multiple exist. In order to achieve the first aim of this PhD, a systematic review needed to be conducted in order to have a starting point to decide on the best ones to choose for psychosocial evaluation. As discussed in chapter 3, this study forms part of the triangulation between the systematic review and the Delphi study in chapter 5.

Aims and Objectives

The purpose of this systematic review is to gather the existing patient reported outcome measures (PROMS) validated on a general cancer population and assess their methodological quality using the COSMIN risk of bias checklist (Mokkink et al., 2018; Prinsen et al., 2018). By narrowing the search to only look at PROMS validated on a

general cancer population and not on cancer-type specific outcome measures, this means that the measures extracted should be appropriate to generalise to all cancer types. The following objectives form the basis of the review:

1. To identify patient reported outcome measures (PROMS) validated on a general cancer population
2. To assess the methodological quality of the scales examining the following nine measurement properties using the COSMIN checklist (Prinsen et al., 2016).
    a. Content validity, structural validity, internal consistency, cross-cultural validity, reliability, measurement error, criterion validity, construct validity and responsiveness.
3. To recommend the psychometrically strongest outcome measures for use in a cancer setting to assess the psychosocial impact of cancer.

Method

Search Strategy

A strategic search of the electronic databases available through the University of Wales Trinity Saint David digital library system was conducted using key words and phrases formed from the literature surrounding psychosocial evaluation of cancer services and the psychosocial impact of a cancer diagnosis. Databases searched included Pro Quest, Pub Med Central, Science Direct, Directory of Open Access Journals, SAGE and Springer Link. A forward citation search on primary results was also performed to explore further eligible studies, all of which were assessed against inclusion and exclusion criteria. Please see Table 3, for a summary of the search strategy used for this review, including details of the databases, keywords and inclusion and exclusion criteria.

The systematic review focused specifically on patient reported measures validated on a cancer population only and excluded measures developed for specific types of cancer or treatment. This was due to the sheer volume of validated measures that exist to represent the many facets of cancer and its treatments, with an aim to find the most inclusive psychosocial outcome measures for people affected by cancer. This would allow the creation of a generic cancer 'toolkit' that could provide an overall baseline for those individuals.

Table 3

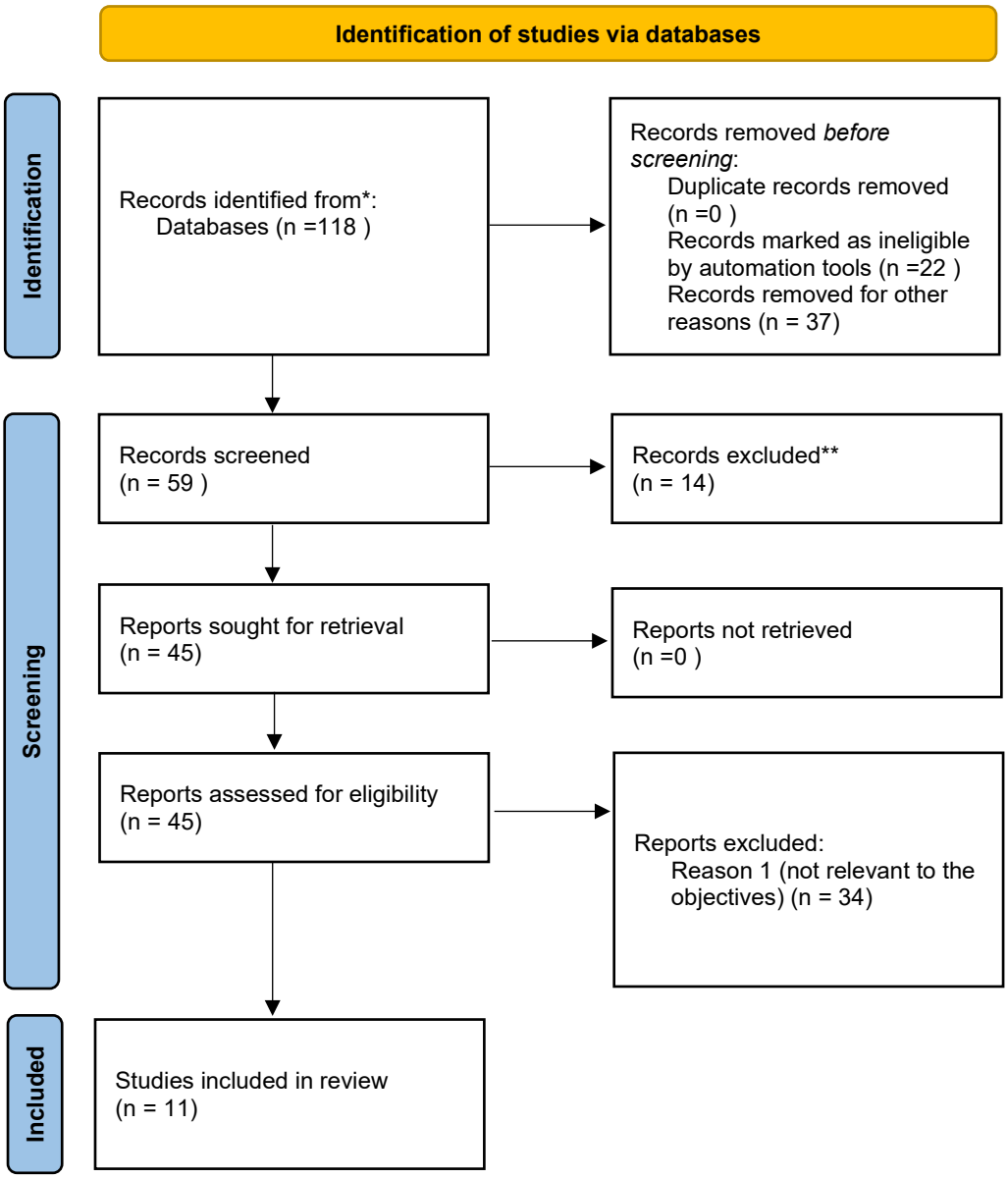
Search strategy outline

Databases searched: Pro Quest, Pub Med Central, Science Direct, Directory of Open Access Journals, SAGE, Springer Link
Search terms: **ANY FIELD** Psychosocial impact of cancer ***AND*** **ANY FIELD** Scale ***AND*** **ANY FIELD** Quality of life ***AND*** **TITLE** Validation ***AND*** **TITLE** Cancer
Inclusion criteria: Primary research, general and disease specific (cancer) PROMS, research participants can be directly/indirectly affected by cancer (family, caregivers), questionnaires had to be filled in by patients, studies and scales published in English, must report psychometric properties of scale validation, full text online, peer reviewed.
Exclusion criteria: Symptom and treatment specific PROMS (to allow the focus to be on cancer as a whole disease rather than individual cancer types), secondary data, systematic reviews, meta-analyses (to allow for in-depth details of outcome measures to be explored), language specific validation, additional modules

Following the data extraction process which can be seen in Figure 10, the remaining papers reporting the validation of a PROM were examined for their measurement properties and evaluated against the COSMIN standards for quality outcome measurement. A total number of 11 papers were included in the final analysis of the systematic review

Figure 10

Data extraction process



Measurement properties

The full details of the COSMIN process and checklist are reported in chapter 3, but a summary of the measurement properties is included here in table 4.

Table 4

Summary of measurement properties

Reliability	**Concerned with the extent to which scores remain unchanged when the scale has been repeated** **Test-retest and intra-rater**	
Internal Consistency	Concerned with how well the items within a scale are correlated with each other. Produces Cronbach's α	
	Measurement error	Concerned with the error of score that is not attributed to true change
	Reliability	Concerned with true changes
Validity	Checks the extent to which a questionnaire is measuring what it set out to measure	
	Content validity	Concerned with whether the content reflects the construct being measured
	Criterion validity	Compares to the gold standard, difficult if one doesn't exist
	Construct validity	Determined by correlations, factor analysis and regression models
	Structural validity	Determined by factor analysis to see if the scores are an adequate reflection of the dimensions
Hypothesis Testing	Concerned with how the measure relates to other measures	
	Cross-cultural validity	Measures performance when translated or culturally adapted
Responsiveness	Concerned with the ability to detect change over time	
	Interpretability	Concerned with the ability to attribute qualitative meaning to quantitative scores

For the purpose of this review and following guidance from the Consensus-based Standards of health Measurements Instruments (COSMIN) taxonomy (Prinsen et al., 2016; Mokkink et al., 2010), measurement properties were divided into three overall domains; reliability, validity and responsiveness examining a total of nine measurement properties. The COSMIN checklist consists of nine boxes with 5-18 items pertaining the standards for methodological quality within that measurement property. Each of the items within the box for the corresponding measurement property is rated on a four-point scale; very good, adequate, doubtful and inadequate. The overall score for the measurement property was determined on a 'worst score counts' method, meaning one lower scored item would bring down the overall rating of the measurement property. The methodological quality of a study was determined per measurement property. The full details of the ratings for each measurement property against the validated questionnaires that were extracted can be found in Table 6 .

Results

The search strategy identified 118 articles following a systematic process of applying specific inclusion and exclusion criteria which left 13 measures eligible for review. Articles were published between 1997-2018, reported on the validation process and psychometric properties of an outcome measure, validated on a cancer population, published and validated in the English language. It was important to exclude cancer (symptom) specific outcome measures as these cannot be used on a general cancer population and measures were also excluded if they were not self-administered, or patient led.

Objective One: PROMS validated on a cancer population following strict search and exclusion criteria

There were 11 validated psychosocial measures eligible for review which assessed a range of psychosocial outcomes related to the impact of a cancer diagnosis, treatment and survival. Table 5, presents an overview of each PROM, describing the constructs measured and their associated psychometric properties. All measures were administered in questionnaire format, through a range of channels including online postal and structured interviews. There are a range of constructs being assessed across the measures which can be considered psychosocial factors; however, some measures include additional factors such as physical symptoms, treatment satisfaction and relationship with health professionals. Some of the psychosocial factors being measured include anxiety, depression, emotional health, loneliness, psychological and social functioning, post-traumatic stress symptoms, social support, hope, cognitive distress, psychological distress, coping and fear.

Table 5

Overview of PROMS and psychometric properties

PROM	Year	Items	Constructs/Domains	Cronbach's Alpha		
Functional Assessment Cancer Therapy – General (FACT-G)	1993	33-items Five subscales Measuring general cancer quality-of-life (QoL)	Physical Functional Social Emotional Relationship with doctor Total	α=0.82 α=0.80 α=0.69 α=0.74 α=0.65 α=0.89		
Quality of Life Questionnaire (QLQ-C30)	1998	Psychosocial function 30-items Five multi-functional subscales	Physical Role Emotional Social Cognitive functioning	Weighted kappa's calculated		
Hospital Anxiety and Depression Scale (HADS)	2000	14-items Two subscales (anxiety (7) depression (7)	Anxiety Depression Overall	Sample1 T1 α=.82 α=.79 α=.86	Sample1 T2 α=0.84 α=.77 α=.86	Sample2 α=.89 α=.82 α=.91
Hope Differential-Short (HDS)	2004	9-items Assessing experience of hope in advanced cancer	Authentic Spirit Comfort Overall	α=.83 α=.69 α=.83		
Post-Traumatic Stress Checklist (PSCL)	2004	17-items Three symptom clusters	Re-experiencing Avoidance/numbing Arousal Total	α=0.74 α=0.75 α=0.77 α=0.88		
Fear of Cancer Recurrence Inventory (FCR)	2009	42-items Seven factors	Total Triggers Severity	α=0.95 α=0.90 α=0.89		

PROM	Year	Items	Constructs/Domains	Cronbach's Alpha	
			Psychological distress Coping strategies Functioning impairments Insight Reassurance	α=0.86 α=0.89 α=0.91 α=0.80 α=0.75	
Comprehensive Needs Assessment (CNAT)	2011	59-items Needs assessment tool Seven factors	Health care staff Psychological problems Physical symptoms Information Social/Religious/spiritual support Practical support Hospital facilities and services	α=0.97 α=0.94 α=0.91 α=0.93 α= 0.86 α=0.80 α=0.85	
Connection to the experience of cancer scale (CONNECS)	2012	10-items Three domains	General closeness Resemblance Cognitive processing Total	Sample 1 α=0.74 α=0.66 α=0.42 α=0.73	Sample 2 α=0.73 α=0.66 α=0.44 α=0.71
Cancer Assessment for Young Adults (CAYA)	2013	90-items Six domains, 16 subscales Health-related QoL young men with cancer	Physical Sexual Intrapersonal Social-relational Educational-vocational-avocational Spiritual	α=0.80 α=0.70-0.76 α=0.78-0.89 α=0.78-0.91 α=0.85-0.88 α=0.87	
Survivor Unmet Needs Survey (short form) (SUNS-SF)	2014	30- items Four Domains Assessing unmet needs amongst cancer survivors	Information Financial concerns Access and continuity of care Relationships and emotional health	α=0.85 α=0.90 α=0.90 α=0.95	
Holistic Well-being Scale	2015	30-items 5 factor structure Novel 3 factor structure	Emotional vulnerability Body irritability Spiritual disorientation Non-attachment Mindful awareness General Vitality	α=0.75 α=0.80 α=0.65 α=0.67 α=0.77 α=0.79	

PROM	Year	Items	Constructs/Domains	Cronbach's Alpha
			Spiritual self-care Blissful-self Disturbed-self Embittered-self	α=0.58 α=0.87 α=0.88 α=0.70
The Cancer Loneliness Scale (CLS)	2017	7-item unidimensional scale measuring loneliness following cancer diagnosis	Cancer-related loneliness	α=0.94

Objective two: Evaluating the methodological quality of the PROMs identified using the COSMIN standards

In Table 6, COSMIN checklist scores are presented, assessing the methodological quality of 11 validated scales based on nine measurement properties reported within the published paper. Out of 11 PROMs, one reported on all nine measurement properties, the most frequently reported measurement properties were content validity, structural validity, internal consistency, reliability, and construct validity. Cross-cultural validity, measurement error and construct validity were reported the least amongst the measurement properties. PROMs were identified based on the original development and validation process of that measure and thus subsequent studies using the measurement instrument were not sought for further evidence. Measurement properties were given one of four overall ratings; 'very good', 'adequate', 'doubtful' and 'inadequate' by using the scoring instructions provided my Mokkink et al., (2018). Under these instructions, a 'worst score counts' method was applied which meant that each measurement property receives a rating representative of the lowest score within that category. For example, where reliability is made up of eight statements which can be rated, if one out of eight statements receive an 'inadequate' rating, then reliability is rated as inadequate overall for that PROM.

Table 6

COSMIN scores for each measurement property rated in the review process

MEASUREMENT PROPERTIES									
PROM	Content Validity	Structural Validity	Internal Consistency	Cross-cultural Reliability	Measurement Error	Criterion Validity	Construct Validity	Responsiveness
CLS		V	V		D			V	
SUNS-SF	D	A	V		A			V	
FACT-G	V	V	V	V	A	V	V	V	V
PSCL		V	V		I	V	V	A	
CONNECS	D	V		V	V	V		I	
CAYA	I	V	V		V	V	V		V
HADS	D	A	V		A			V	V
HWS	D	A	V	I	D		V	V	A
QLQ-C30	D	V	V		D	D		V	V
CNAT	D	A	V		A			A	A
FCRI	D	A	V		A		V	V	V

Note: V=very good A=adequate D=doubtful I=inadequate, no rating denotes property not reported within that study

Content validity was the lowest rated measurement property across almost all PROMs reviewed, this concerns itself with the generation of question content, relevance and piloting with an appropriate target audience. Given that the scope of the review focussed on the original validation process of a particular PROM, some of the earlier measures (dates ranged from 1993-2017) did not see some of the thorough piloting processes that the later measures used. For example, early measures developed their items with experts, and later measures had more patient involvement. This is reflected in their lower scores for content validity. Despite the earlier measures scoring lower in this

category, they are still regularly being used in the present day for evaluating the impact of a cancer diagnosis. Overall, most PROMs had good ratings for structural validity and internal consistency, showing that the appropriate methods (confirmatory factor analysis and Rasch analysis) were used to test whether items within the scale related to each other and that they were all measuring the same underpinning constructs.

PROMS identified and evaluated by COSMIN standards

The Cancer Loneliness Scale (CLS: Adams et al., 2017)

The CLS is a 7-item unidimensional scale measuring loneliness following a cancer diagnosis. The scale was developed based on loneliness theory, previous general loneliness measures and qualitative studies of loneliness in a cancer population. It allows people to answer each question based on a five-point scale ranging from one (never) to five (always). This scale specifically measures how often individuals feel lonely or isolated at different points of their cancer journey. An example statement is *'how often does your cancer diagnosis make you feel isolated from others?'* There was good evidence to show that this is a unidimensional scale. Internal consistency was rated as very good and produced a Cronbach's α of 0.94. There was very good evidence for construct validity and structural validity as confirmatory factor analysis was performed. There was existing, but low evidence for the reliability of this measure deeming it doubtful in the COSMIN standards. There was no evidence reported in the development paper evaluating content validity, cross-cultural validity, measurement error, criterion validity or responsiveness, giving these measurement properties and indeterminate rating.

Short-form Survivor Unmet Needs Survey (SF-SUNS; Campbell et al., 2014)

The SF-SUNS is a 30-item scale consisting of four domains measuring unmet needs amongst cancer survivors. The four domains include information needs, financial concerns, access and continuity of care and relationships and emotional health. There was

very good evidence for internal consistency with Cronbach's α for each domain ranging from 0.85-0.95. There was adequate evidence for the evaluation of reliability and structural validity, and doubtful evidence for content validity. Construct validity was very good as a factor analysis was performed and compared with the original factor loadings for the full version of the SUNS. Measurement error, criterion validity, responsiveness and cross-cultural validity were not evaluated or reported in this development paper.

Functional Assessment of Cancer Therapy – General (FACT-G: Cella & Tuskey, 1993)

The FACT-G is a 33-item scale measuring quality of life in a general cancer population. The FACT scale has had many revisions to develop new chapters to reflect specific cancer types and treatments, but this scale is eligible for use with all cancers. It measures quality of life through five subscales including physical, functional, social, emotional, relationship with doctor and provides a total score for overall quality of life. The FACT-G has very good levels of evidence for almost all measurement properties reported in this development paper, with very good internal consistency with Cronbach's α for each subscale ranging from 0.65-0.89. Out of each of the scales being assessed for this review, the FACT-G reported the most thorough development process evidencing strong results for each measurement property. Reliability was the only measurement property with adequate evidence in regard to administration methods and environment not being reported fully. This scale had the strongest levels of evidence from this development paper.

Post-Traumatic Stress Checklist (PSCL; Duhamel et al., 2014)

The PSCL is a 17-item checklist assessing three symptom clusters associated with the DSM IV classification of post-traumatic stress disorder. This scale has been specifically developed for use within a cancer population and in this development paper it focuses on survivors. The three symptom clusters it focuses on are re-experiencing, avoidance/numbing and arousal. The scale also allows for a total scale score. The PSCL has very good evidence for internal consistency with Cronbach's α ranging from 0.74-0.88

and structural validity due to performing a confirmatory factor analysis. The evidence for reliability is inadequate and adequate for construct validity. Measurement error and criterion validity are reported as having very good levels of evidence. Content validity, responsiveness and cross-cultural validity were not reported or evaluated in this development paper. The overall quality of evidence for this scale is moderate, it has a strong foundation from its construction but requires more testing to strengthen reliability and validity.

Connection to the Cancer Experience (CONNECS; Hawkins et al., 2012)

The CONNECS was developed to measure the connection to the cancer experience through a family member or friend. It is a 10-item questionnaire measuring three domains (general closeness, resemblance and cognitive processing), and gives a total score representing degree of closeness. This outcome measure is appropriate for family members and friends of those who have experienced cancer, although not tested directly on a general cancer population, it was included in the review due to the wider aims of the thesis including the impact on family and friends of those with cancer. This outcome measure was developed for use within genetic testing/counselling sessions to help ascertain the live experience of cancer from a family/friend viewpoint, questions include asking whether their experience has influenced their own health behaviours.

Cancer Assessment in Young Adults (CAYA; Hoyt et al., 2013)

The CAYA is a 90-item scale measuring health-related quality of life in young adults with cancer. It covers six domains including physical, sexual, intrapersonal, social-relational, educational-vocational-avocational and spiritual.

Hospital Anxiety and Depression Scale (HADS; Johnston, Pollard & Hennessey, 2000)

The HADS is a 14-item scale made up of items representing anxiety and depression. The scale is split into two subscales (Anxiety and Depression) with seven items

each and answered using a four-point rating scale. Individuals are given a score for anxiety, depression and an overall total score for emotional distress. Zigmond and Snaith (1983) originally developed the outcome measure to help detect these issues in people with physical health problems. The Johnstone et al., (2000) performed exploratory factor analysis to explore the strength of the items and subscales in a cancer population across two samples, with the first sample being repeated a second time. Upon examination within the Johnstone et al., (2000) validation paper, it reports HADS as having good internal consistency with Cronbach's α ranging from .77-91 across both samples and time points, it was given a very good rating as per the COSMIN guidelines. It also has very good construct validity and responsiveness but reports adequate structural validity and reliability and doubtful content validity. There was not enough detail in this paper to report on the other measurement properties.

Holistic Well-being Scale (HWS; Lee, Fan & Chan, 2015)

The holistic wellbeing scale is a 30-item questionnaire with a seven-factor structure which focuses on supporting and promoting personal well-being in oncological care. It measures, emotional vulnerability, bodily irritability, spiritual disorientation, non-attachment, mindful awareness, general vitality and spiritual self-care. They also explored a novel three factor structure focusing on the self; blissful-self, disturbed-self and embittered-self. This paper focuses on testing the psychometric properties of the original seven factor structure and exploring the potential for a stronger, three factor scale. In this paper the seven-factor structure reports an acceptable range of Cronbach's α (0.58-80) and the three-factor structure reports a much higher range (.70-.88). As per the COSMIN guidelines the HWS reports very good internal consistency, criterion validity and construct validity; adequate evidence for structural validity, doubtful evidence to support reliability and content validity; and inadequate evidence to support good cross-cultural validity (translated into Chinese in this instance).

Quality of Life Questionnaire (EORTC QLQ-C30; McLachlan, Devins & Goodwin, 1998)

The European Organisation of Research and Treatment of Cancer (EORTC) developed this quality-of-life questionnaire (QLQ-C30) to quantitatively measure health-related quality of life originally for use in clinical trials of cancer patients. The QLQ-C30 is a 30-item scale with five multi-functional psychosocial subscales (physical, role, emotional, social and cognitive functioning) and three multi-item symptom scales (fatigue, pain and emesis, global health/quality of life) and six single items (financial impact, dyspnoea, sleep disturbance, appetite, diarrhoea and constipation). The purpose of the QLQ-C30 is to gain understanding of the impact of cancer and its treatments on everyday functioning. The QLQ-C30 is a core outcome measure for general cancer, additional modules have since been developed for specific cancer sites and treatments. The 1998 McLachlan validation paper focuses specifically on evaluating the performance of the psychosocial subscales, the original development paper of the whole measure could not be sourced. Using this paper, the QLQ-C30 scores very good on structural validity, internal consistency, construct validity and responsiveness. It scores a much lower value of doubtful for content validity, reliability and measurement error and no evidence to support the evaluation of the remaining measurement properties. The QLQ-C30 is a widely used measure in oncological research for assessing quality of life however some of the lower results could be due to this not being the original development paper and being over 10 years old. The EORTC however have an up-to-date validated version of the QLQ-C30 core measure which they recommend for use in cancer populations.

Comprehensive Needs Assessment Tool (CNAT; Shim, Lee & Park et al., 2011)

The CNAT is a 59-item needs assessment tool with seven domains measuring needs about: health care staff, psychological problems, physical symptoms, information, social/spiritual support and practical support. Developed using the EORTC Quality of Life guidelines, it attempts to capture a comprehensive overview of needs in a general cancer

population through all phases of the cancer trajectory. This makes it a good outcome measure for documenting changes and needs over time. It has very good internal consistency with Cronbach's α ranging from α= .80-.97. Apart from content validity, which was scored as doubtful, the remaining measurement properties all had adequate supporting evidence, although missing evidence for cross-cultural validity, measurement error and criterion validity.

Fear of Cancer Recurrence Inventory (FCRI; Simard & Savard, 2009)

The FCR is a 42-item multidimensional scale measuring seven factors of fear associated with the recurrence of cancer following an all-clear diagnosis. These factors include triggers, severity, psychological distress, coping strategies, functioning impairments, insight and reassurance and are rated using a 4-point Likert scale (0=not at all, 4= all the time). Internal consistency is rated very good with Cronbach's α ranging from .75-.95. The FCRI also had a very good rating for criterion validity, construct validity and responsiveness, structural validity and reliability were rated as adequate and content validity as doubtful. The remaining measurement properties were not examined in this development paper. There are many scales developed to measure fear of cancer recurrence, but they have mostly been validated for use on breast cancer patients, the FCRI (Simard & Savard, 2009) is acceptable for use in a general cancer population.

Objective three: recommend the psychometrically strongest outcome measures validated for a cancer population

Following the use of the COSMIN guidelines which allowed each measurement property within a prom to receive an individual rating, a new scoring system was developed to allow the PROM to be given an overall numerical value. This made it easier to assess which of these PROMs performed better overall based on the evidence in the validation paper. By

assigning a value to the four ratings given by the COSMIN checklist, the proposed new scoring system assigns a value of zero to four for each rating. For example, very good = 4, adequate = 3, doubtful=2, inadequate=1 and where the measurement property is not reported, it would receive no score (zero). If each measurement property were to receive a rating of 'very good' then it would achieve a maximum score of 36, therefore each instrument will have a score of X/36. By using this system, the instruments can be ranked, as shown in Table 7.

Table 7

Ranking of PROMS based on new proposed scoring system

Instrument	Overall score /36	Measurement properties reported and evaluated /9
FACT-G	35/36	9/9
CAYA	25/36	7/9
FCRI	24/36	7/9
HWS	23/36	8/9
QLQ-C30	22/36	7/9
HADS	20/36	6/9
PSCL	20/36	6/9
CONNECS	19/36	6/9
SUNS-SF	16/36	5/9
CNAT	15/36	6/9
CLS	14/36	4/9

From this scoring system FACT-G performs marginally better than the other instruments, with some of the other instruments being closer in range. Table 7 shows that the CLS scores the lowest, however it was also the one which had the least amount of measurement properties reported within its validation paper. Eight out of the 11 instruments performed poorly on content validity, with only FACT-G being given a very good rating. The constructs being measured within these instruments all had good Cronbach's α so were all taken forward to be used in the Delphi consensus building study. By using the COSMIN method in addition to the overall scoring method proposed to give

each measure a total score pertaining to all of their methodological properties, it allows the suggestion that FACT-G is the psychometrically strongest outcome measure to use in a cancer population, measuring attributes relating to the physical, social and psychological functioning related to a cancer diagnosis.

Discussion

The purpose of this review was to identify existing PROMs validated on a general cancer population and assess their methodological quality using the COSMIN risk of bias checklist (Prinsen et al., 2016; Mokkink et al., 2010) in order to recommend the psychometrically strongest measures to be used in the psychosocial evaluation of cancer support services. Eleven disease specific measurement instruments validated on a cancer population, measuring aspects of psychosocial health, were identified in the review process. Articles were specifically sourced which reported on the development of a questionnaire and subsequent validation on a cancer population. By using the COSMIN risk of bias checklist, it allowed each measure to be evaluated on nine individual measurement properties and given a rating to reflect how well it performed on that measurement property. Also contained within the COSMIN process is the ability to rate the overall levels of evidence for that outcome measure, however this was not completed as part of this review as the focus was to examine the development and validation process of that measure and its properties and instead a new scoring system was proposed to allow an overall score to be given to each PROM.

The initial search strategy yielded 118 PROMS, however following the strict inclusion and exclusion criteria this left eleven measures to be evaluated. However, a lot of the articles retrieved were duplicates or not relevant to the aims of the review. The decision was made to focus the review specifically on PROMS that had been validated for use on/with a cancer population in order to make sure they were the most appropriate for the target population. The attributes being measured across all eleven PROMS were consistent

with the literature surrounding the impact of a cancer diagnosis and many of these were often overlapping with each other, thus supporting the need to define which measures are more psychometrically robust. Anxiety, Depression, Distress and variants of these attributes (low mood, worry and mood state) were frequently measured (Lankin & Slavich, 2014; Pitman et al., 2018) including the HADS which exclusively measured anxiety and depression as individual constructs. These attributes were found in over half of the PROMS identified, including the HADS, FACT-G, FCRI, CNAT, SUNS-SF and QLQ-C30. This is supported by a review by Hess and Chen (2014) who found a high frequency of reporting anxiety and depression in cancer populations. Aspects of social support, loneliness, maintaining friendships and relationships were also attributes that were measured amongst five of the PROMS, found in FACT-G, QLQ-C30, CNAT, CAYA and the CLS. This is supported by Lankin and Slavich (2014) who suggest that social support and individual environment plays a crucial role in an individual's ability to cope with a cancer diagnosis. Despite most PROMs focussing on psychosocial health needs of individuals with cancer, many constructs also accounted for some of the physical impacts and consequences of a cancer diagnosis. Attributes such as pain, discomfort, energy levels, symptom progression and appetite were included in some PROMS as part of establishing overall quality of life and levels of coping with the illness. This is not surprising due to PROMs being introduced as standard procedure in clinical trials to allow clinicians to gain a better understanding of the impact that cancer and its treatment or symptoms have on an individual (Jayakumar et al., 2017).

The outcome of the review indicated that the overall strongest measure was the FACT-G. It scored the highest on almost all measurement properties as per the COSMIN standards and reported on all nine measurement properties which allowed it to receive a full evaluation. The FACT-G is an overall quality of life measure for individuals with cancer that includes five subscales and an overall QoL score. The constructs measured

within this PROM overlap with the QLQ-C30 which was also identified in the review. Despite the QLQ-C30 scoring lower overall, both measures performed well for structural validity, internal consistency, construct validity and responsiveness, suggesting that the similarities between the measures are important for this population. As seen in Table 6, the strongest measurement property overall was internal consistency, this shows that each measure performs well on achieving the outcomes that it set out to measure (Frost et al., 2007; Prinsen et al., 2016). Content validity was the lowest rated measurement property overall suggesting that although internal consistency was high, each measure may not be as representative as possible of the proposed domains. Cross-cultural validity was the least reported measurement property across all PROMS, this may be due to the majority of populations within the PROMS examined being American and British. Many authors publish separate cross-cultural validations of PROMS following its development, so a future recommendation would be to include cross-cultural in the inclusion criteria to allow these to be examined.

Part of the COSMIN evaluation looked at whether the measured was developed with and validated on an appropriate target audience, in this case, individuals with cancer or experience of cancer. A crucial part of this review was to extract PROMS that were validated on a cancer population, however two of the PROMS were not developed with patients or professionals but were instead guided by the literature so therefore scored lower by the COSMIN standards (CONNECS and HADS). Involving people with cancer in the development of these measures, as they are the target audience, is believed to lead to higher quality outcomes (Wilson et al., 2018; Rosenkautter et al., 2017) and are of a higher methodological standard. Prior to applying exclusion criteria, many PROMS were identified which were reporting on the use of a measure with a cancer population, rather than reporting on the validation of that measure. This lends itself to both a criticism of the review and also the field of psychological measurement. It may have allowed some useful

PROMS to be left out of the review process that are currently used in the field, however it means that the psychometric properties of these measures are being checked after they've already been utilised in this population, instead of going through an in-depth development and piloting process with the target population. This leads to an additional critique of the selection process for the T:POT measures. A key feature of assessing quality via the COSMIN checklist is through patient/target audience involvement. Throughout the thesis there are elements of patient involvement documented and subsequently critically reflected on in chapter 8. There was no patient or public involvement in identifying or reviewing the measures extracted from the systematic review. As there was no success in setting up a steering group, there was no access to the appropriate population in the required time frame. In hindsight this could have been a valuable step to add as it would support the idea that patient/target audience involvement is a key part of assessing quality.

The COSMIN risk of bias checklist was chosen to evaluate the methodological quality of each PROM extracted in the review process. The process of using the COSMIN checklist was very thorough but quite time consuming. However, considering one of the main objectives of the review was to evaluate methodological quality, it was not surprising that this was a lengthy process. Other methods of evaluation were considered (SACMOT and EMPRO), however the COSMIN stood out to be the gold standard which was important for the wider aims of the PhD. There are two parts to the COSMIN standards, the risk of bias checklist and the overall levels of evidence process. A decision was made not to complete the overall levels of evidence process due to the nature of the review focusing on the initial development and validation of a PROM, the overall levels of evidence process is better set up for examining quantitative studies utilising the PROM in psychosocial research. This led to a new proposed scoring system which allowed each PROM to be given an overall score based on how it performed on the measurement properties evaluated. There is a ten-point difference between the FACT-G as the highest

scoring PROM and the next PROM. A limitation of the COSMIN checklist is that, even if a PROM performed really well on a measurement property, its overall score is brought down if it is not perfect. In addition to this a limitation of the new proposed scoring system does not reflect the strengths of each PROM. For example, the CAYA performed very well on almost every measurement property that it reported on, however it did not report on two of the properties and therefore received a zero for each one. When reflecting on the process of using the COSMIN checklist and making the decision not to use the overall level of evidence tool within the COSMIN, it is noted that it could have enabled a more thorough examination of the measures identified. Using the overall level of evidence tool would have allowed the measurement properties of each scale to be examined in a higher quantity of studies, which may have altered their overall score. The overall level of evidence method would establish the frequency of the use of each measure, in turn it would probably have an impact on its overall reliability, validity and utilisation. Therefore, the measures chosen only represent a single published study, which reported on the development of the scale and allowed for a baseline level of quality to be established. Future work could look at each measure individually and assess the level of evidence available to have a more in-depth understanding of the quality of that measure.

The self-regulation model and the T:POT

As outlined in Chapter two, the self-regulation model (Leventhal, 2016) underpins the research conducted in this thesis as it helps us to understand how individuals appraise their own health threats and how they cope with that threat. This is relevant because psychosocial interventions are designed to help people cope and it is important to understand whether they are improving an individual's outcomes. Research provided by Hagger and Orbell (2022) supports that this model is important for understanding and encouraging engagement with coping and prevention strategies and helps to understand the

link between an individual having more control/curability over their illness/stress (Leventhal et al., 2016) and better outcomes. Further support for the importance of self-assessment comes from Cuthbert et al. (2022) who identified a range of self-management interventions for people with a cancer diagnosis, which they determined should focus on empowering people with the education about their illness (controllability) and the skills to enable them to cope. Self-assessment is directly linked to PROMS and to the stress and coping framework whereby an individual is self-assessing their thoughts, feelings and behaviours. The measures identified in this thesis not only help to measure an individual's self-assessment but can be mapped across the focus for self-management strategies and the elements of the self-regulation model.

The following section outlines how the measures identified for the T:POT can be mapped across each element of the self-regulation model, demonstrating how each facet of the model can be explained and assessed using these measures. This is not isolated to these measures, but should demonstrate how research can be better informed by choosing the most appropriate measures that represent the underpinning theory. Each of these measures aims to measure and subsequently evaluate factors related to psychosocial health and coping with cancer. The self-regulation model is important to understanding the use of PROMS due to the overlap in self-assessment elements. They both rely on an individual's ability to self-assess, self-report and appraise their needs, emotions, behaviours, and symptoms. How each of the measures identified within the toolkit can be mapped across the various elements of the self-regulation model is discussed further below, focusing on how the model would respond for cancer specific stress/illness. It is important to note that the models of stress and coping discussed in this thesis are not cancer specific and account for all stress and illness in general, representing an overall stress and coping response. The measures identified are specific to cancer and thus everything will be anchored towards coping with cancer as a stressor.

The first measure being discussed is the FACT-G which can be considered an overall quality of life measure of general cancer. Overall this measures four subscales including emotional, social, physical, and functional wellbeing. It asks individuals to report how they cope with their emotions and their physical symptoms and asks them to describe their illness representations through all four subscales. Representation of Emotional Reaction and Coping Behaviour for Emotional Control, as found in the SRM is measured mostly in the EWB subscale. This subscale focuses on an individual's worries and feelings about their condition worsening or about dying. The FACT-G measures overall quality of life in people with cancer, requiring them to self-assess the various aspects of their wellbeing and how they may be coping with the impact of their cancer in the last seven days. The four subscales allow various aspects of the illness representations element to be assessed, asking people about their physical symptoms, how they perceive the severity of their illness and how much control they have over it. Using this measure to evaluate an intervention allows a wide range of emotional reactions, illness representations and coping outcomes to be evidenced. Quality of life research is a heavily documented area within the cancer field, and as discussed in chapters 2 and 3, many tools exist to capture an individual's perspective of their quality of life over a specific time frame. This measure works well to mirror the SRM as it can be viewed as a cyclical process. An individual will constantly reappraise their situation, just as an intervention could review and reassess and individual's perception of their quality of life.

The second measure being examined in relation to the SRM model is the SUNS-SF. This measure assesses an individual's representation of their unmet needs as a result of having cancer, now or in the past, across four subscales that can be mapped onto the SRM. It asks individuals to assess their level of need across the last month encouraging them to appraise their own coping outcomes for a specific time period. The SUNS-SF subscales measure unmet needs in relation to finances, access to information about their cancer,

coping and emotional needs, and access and continuity of care. All of these can be mapped across the SRM but more specifically onto the control/curability element of illness representations. The unmet coping subscale taps into identity and emotional representations and subsequently coping appraisal. This is an effective measure of capturing how a person feels they may be coping or what elements they may need more support with. It is important to note that this scale is not measuring coping as a unidimensional element, the issues surrounding the measurement of coping are well documented in the literature and throughout this thesis. Given that the SRM explains the process in which people form a coping response, the unmet coping subscale of the SF-SUNS helps to understand an element of the coping response. Again this is representative of the individual's interpretation and self-assessment, relying on their understanding of what it means to be coping with stress/illness and how to convey it. This subscale specifically asks a range of questions to capture coping, which are arguably not enough to fully capture how an individual is coping but whilst trying to keep this measure short, it captures an element from multiple facets of coping. The SF-SUNS is also relevant to the SRM as the model also requires individuals to explore the resources available to them in order to form their coping response, the SF-SUNS asks people to assess their needs across the different subscales to highlight where they may or may not need more support.

The final two scales are more specific than the previous two. Whereas the FACT-G and the SF-SUNS focus on overall QoL and overall unmet needs, the final two focus on more specific facets of the impact of cancer. This means that they map across the SRM far less significantly but this does allow for less repetition. The third measure considered is the Cancer Loneliness scale (CLS) which can be mapped across the emotional representation and coping behaviour for emotional control pathway. This measure asks about a person's relationships with the people around them in relation to their cancer and how supported they feel. This mostly maps across the emotional representations of the

SRM although could also map across the consequences aspect of illness representations. How supported an individual feels following a stressful event forms part of their assessment of resources and forming their coping response.

Finally, the last measure to be discussed is the Fear of Cancer Recurrence (FCR) scale which largely focuses on emotional representations and how much fear, worry and anxiety a person has about the possibility of their cancer recurring, or developing another cancer. Similarly to the FACT-G this measure also maps across the curability/control and consequences element of illness representations. It also asks individuals about the strategies they may use to cope with the feelings they have about developing another cancer, allowing coping outcomes to be appraised. Worry is a large contributor to anxiety in general and this may contribute to an individual's ability to perceive their stressor as a challenge, and they may continuously see it as a threat. As previously discussed, a stressor that is seen as a challenge reaps positive outcomes and a stressor that is seen as a threat reaps more negative outcomes.

Using these measures to assess the impact of a psychosocial intervention allows a range of cognitive and emotional illness representations to be evidenced. The Self-Regulation Model (as discussed in chapter 2) is a useful model for helping to understand how an individual forms a representation about their illness and how they might attempt to cope with it, and the measures within the T:POT support this being evidenced across multiple aspects of psychosocial health. The Illness Representations Questionnaire (IPQ) is a measure that was directly developed to measure the elements of the self-regulation model. However, despite directly measuring a person's illness representations, it does not measure psychosocial impact. Therefore, it would not be appropriate on its own for this research but it would be a beneficial addition to the toolkit in future to allow for a more in-depth analysis to take place, exploring how an individual's illness perceptions may change over time, change following intervention, and link to their overall outcomes.

In summary, the measures identified for T:POT help to demonstrate how the self-regulation model can be used as a framework for understanding and explaining the psychosocial impact of an intervention designed to support an individual with cancer and not just the coping process. The original final study of this PhD work would have allowed an insight into whether the intervention being evaluated contributed to the understanding of how people cope with their illness. However, as this study ended up being a much smaller scale test of the T:POT, it is difficult to draw that conclusion. However, by mapping these measures across each domain of the self-regulation model it suggests they provide a good fit. Each of these measures require an individual to assess their own health status based on four key outcomes (quality of life, unmet needs, loneliness, and fear of recurrence), which is what the self-regulation model is based on; that individuals must conduct a self-assessment of one's resources and appraisal of the outcome.

Conclusion

This review set out to identify PROMS validated on a cancer population and examine their methodological quality in order to determine which of these would be the psychometrically strongest to use in psychosocial research. The review highlighted that there is no one perfect outcome measure and it is not possible to measure all of the attributes associated with the impact of a cancer diagnosis with one outcome measure. This therefore means that a combination of outcome measures may be required and some sacrifices in quality may have to be made if using measures developed by other researchers. The findings of this review contribute to the second phase of the PhD project which looks at the attributes within these PROMS in more detail. The COSMIN standards highlight the importance of ensuring that a good measure should be developed with input/feedback from the target population it its development stages. This was therefore a crucial step in the process of developing the final toolkit of measures. Accordingly, the findings of the review reported within this chapter were used to inform the first empirical study of the thesis reported in the next chapter, an online modified Delphi consensus building study. This next study specifically targeted those with experience (or "expertise") with cancer, either personally or professionally, in order to reach consensus on the final constructs to be included within the toolkit.

This systematic review forms part of the mixed methods model approach from Green et al. (1989), whereby the results of this review are used as part of the 'complimentary' phase of this model as it directly shapes the Delphi study in the following chapter. The aim of this systematic review was not only to discover what the current measures were for use in a cancer population but to also address some of the issues that arise from the stress and coping literature that discusses the lack of quality assessment within psychological measures and the lack of being able to aggregate the results of studies

due to choosing different outcome measures. This is the first step to achieving a level of consensus about which outcomes should be measured, which is an issue that is documented in the literature surrounding measuring how people cope. This chapter has added to the existing literature on PROMS by examining the methodological quality of those developed for a cancer population and aligning them to stress and coping frameworks to really understand how to effectively measure psychosocial health following cancer.

This chapter has detailed the process undertaken to identify and assess the PROMS suitable for use in a cancer population. In line with the aims of the PhD, the following chapter will detail the next step of choosing the most appropriate measures by engaging key stakeholders in a Delphi consensus building study. This will allow the key constructs of the measures identified in the systematic review to be examined and reviewed for importance and relevance.

Chapter Five: An online modified Delphi study exploring consensus on key psychosocial outcomes for cancer populations

This chapter reports the first empirical study conducted for this PhD and forms part of the preparation phase as outlined in Figure 5. Following the systematic review of the literature surrounding PROMS validated on a cancer population discussed in the previous chapter of this thesis, the constructs within those measures were extracted and examined using a Delphi consensus technique.

A brief history of the Delphi technique

The Delphi technique was originally developed by the RAND Corporation in the 1950s. The RAND Corporation are a non-profit organisation who help to improve policy and decision making through research and analysis ("A Brief History of RAND", 2019). The Delphi technique is a consensus building method using a series of questionnaires and controlled feedback (Dalkey & Helmer, 1963; Day & Bobeva, 2005). The technique requires the use of pre-defined 'experts' within a particular field, to pool together their knowledge to reach a convergence opinion on real world subjects (Baines & Regan de Bere, 2012; Goodman, 2016). The Delphi method is becoming more frequently used within Participatory Action Research (PAR), in PAR participants are viewed as research collaborators who possess the knowledge and agency to contribute to the design and collection of the evidence. Using the Delphi technique within PAR allows the properties of PAR to be honoured (participants involved at each stage and change-orientated research) whilst maintaining confidentiality amongst participants (Fletcher & Marchildon, 2014). The Delphi technique is most commonly used in health research and policy consultations (Boulkedid et al., 2011), with a growing focus on patient and public involvement within research design and data collection (Williamson, Young, Bagley & Gamble et al., 2017).

There are four key elements that inform the design and delivery of the Delphi technique. These elements are described in detail below (Skulmoski, Hartman & Krahn, 2007):

- *Anonymity amongst participants*: this allows for free expression of opinions without pressure from the other group members and prevents group domination. However, some research suggests that it reduces participant accountability and may encourage snap decisions (Fletcher & Marchildon, 2014).
- *Multistage iteration & controlled feedback*: this allows participants to review their answers in comparison to the group summary, controlled feedback informs the participants of the group response as a whole and can offer the option to clarify their responses.
- *Statistical aggregation of group response*: this allows for quantitative analysis of the data, often looking at mean ratings, stability of responses between rounds and percentage of consensus between participants.

It is frequently documented in the Delphi literature about the lack of consistency when conducting or reporting a study which uses the Delphi technique. A systematic review by Boulkedid et al., (2011) explored the use of the Delphi method when determining performance indicators in healthcare. They concluded that there is a large variation in the way that studies using this method of consultation are reported, with many lacking in detail about response rates, feedback processes and the final results following consensus (in this case, the finalised performance indicators). A later review by Diamond, Grant, Feldman, Pencharz and Ling et al., (2014) also supported this by finding that there was still variation in the reporting of Delphi studies, more specifically about what defines consensus and how some studies used reaching consensus to signify the end of the study and others used a pre-defined number of questionnaire rounds. Both reviews and further

research into this issue (Hasson, Keeney & McKenna, 2000; Boulkedid et al., 2011; Davidson, 2013; Diamond et al., 2014) concluded that there is a need for clearer guidelines for the conducting and reporting of Delphi studies and encourage researchers to document the in-depth process they undertake when using this method in their research.

Despite the lack of clear guidelines for employing the Delphi technique, there are assumptions as to what defines the reliable use of the Delphi technique which includes anonymity of panel members, multistage iteration and controlled feedback, and group response (Snape, Kirkham and Preston et al., 2014). The subject of anonymity was heavily criticised during Dalkey and Helmer's (1963;1967) original work as the 'expert' panel members met face-to-face and were known to each other as they had previously worked together on other research projects (Davidson, 2013). The development of the Delphi method being conducted more rigorously lead to researchers modifying the original structure which is often reported in the literature as a modified Delphi (Khodyakov et al., 2016; Kearney et al., 2017). A modified Delphi is further described by Davidson (2013) to include online iterations, groups that focus on policy and electronic decision aids (handheld devices). Most importantly there is a crossover within the definitions of all of these adaptions to the method, therefore all meet the criteria for a reliable modified Delphi technique. The most common modification to the Delphi technique is online delivery. This is referred to as an *Online Modified Delphi* (OMD; Khodyakov et al., 2016) or e-Delphi, where the same stages of iteration and feedback are followed but it is administered online so as to ensure anonymity amongst group members. There are other methods of exploring consensus available, such as *Nominal Group Technique* (NGT; Delbecq & Van de Ven, 1975) however they all required participants to meet face-to face. The advantages of using an OMD include being able to reach a diverse range of people, it is cost effective and time saving as there is no need to travel, individual responses are not influenced by potential

dominating group members and all feedback is anonymised (Fink, Kosecoff, Chassin & Brook, 1984; O'Neill et al., 2018).

Kearney et al., (2017) utilised a modified Delphi which included two online survey rounds and a stakeholder consensus meeting. Expert panel members were given a unique identifier to ensure anonymity and were asked to rate items for importance on a scale of low to critical importance. This continued until they reached consensus on the most critically important items, through this process they identified which topics should take priority when conducting research with patients in clinical trials, a consensus was reached when at least 70% of panel members had agreed on their level of importance. Additional recommendations regarding the number of questionnaire rounds are provided by Black, Murphy, & Lamping (1999; O'Neill et al., 2018) which suggests that the optimal number of questionnaire rounds should be between two and three. This is enough to generate convergence of opinions amongst individuals without having an adverse effect on response rate, as this is likely to happen if there are more than three rounds.

Using the Delphi technique allowed for a good way of involving patients and the general public (PPI) in the research. Cancer Research UK (CRUK) designed a PPI toolkit for researchers which explains that using PPI can improve the quality and relevance of the research being carried out, by involving those who can benefit the most from the research and ensuring the outcomes better reflect their needs. Involving patients in the whole process from planning to dissemination benefits the researcher and the patient population in question. Benefits include the relevance of results, quality of data collected, greater impact, and better recruitment and retention during data collection. The Wales Cancer Research Centre (2017) also supports the use of PPI and promotes it as an active partnership that works together to improve the health and wellbeing of individuals with cancer. It is good practice to involve the target population in the development of any new outcome measure, the aim here was not to develop a new measure but to help make

decisions about which health constructs within these validated scales are the most important and relevant to that target population. The hope is that it would avoid any unnecessary questioning, allow outcomes to be generalised and comparable across different services, provide a more streamlined approach to intervention evaluation, and overall, better reflect the cancer population when evaluating the impact of a support intervention.

There are many validated questionnaire scales available to evidence the impact that an intervention has had on an individual's psychosocial health, especially within the cancer field. The issue with this is that there is an overwhelming amount to choose from. Choosing the most appropriate and effective measurement outcomes is crucial to collecting good quality data that will be the most useful for what you are trying to evidence. In the case of cancer, there are many validated scales dedicated to specific cancer types and treatments as each one will have some unique challenges. However, this becomes difficult when trying to evidence impact in a more general cancer population or compare outcomes across the cancer population. Research on exploring the most appropriate outcome measures, or which key outcomes to measure within a cancer population usually take shape in the form of core outcome sets. Boers et al., (2014) describes a core area as 'A set of defined health concepts related to a specific health condition and setting', a group of these core areas together then make up a core domain for that health issue. An example of using the Delphi method within the lung cancer field to develop core outcome sets was conducted by Mak et al., (2016) who used a modified Delphi approach to reach consensus on a standard set of patient-centred outcomes within the lung cancer population, highlighting survival, complications, degree of health, and quality end of life care as key outcomes to be measured in this population.

Early research from Corner et al., (2007) used the nominal group technique to explore research priorities amongst a UK wide general cancer population. They decided on

a list of 13 research priorities which included impact on life and how to live with cancer, risk factors and causes, early detection and prevention, use and effectiveness of complementary therapies, general education about cancer for the public, side effects, information needs, and other factors related to how the hospital handles health and safety and communication with patients. Research adding to this comes from Howell et al., (2013) who explored consensus on what the most important research priorities are amongst a Canadian cancer population, they concluded that physical health, emotional health, social health and quality of life were the most important outcomes to measure within that population. The most important factors within physical health included symptom experience, sleep hygiene, nausea, pain and fatigue; emotional health included anxiety, depression, psychological adjustment, coping, body image, spirituality and subjective wellbeing; important social health factors included social function and social support and relationships. Finally, overall quality of life was included as an important separate outcome to be measured within this population. Niedzwiedz et al., (2019) provide support for anxiety and depression being included as research priorities from their systematic review of common mental disorders amongst people living with and beyond cancer. Anxiety and depression were the most commonly cited problems associated with the psychosocial impact of living with cancer and this is supported in the wider literature (Pitman et al., 2018; Walker et al., 2013). Even without a prior psychiatric history, a cancer diagnosis can make people more susceptible of experiencing anxiety and depression which can have adverse or less favourable treatment and recovery outcomes (Zhu et al., 2017) and for those who have a previous history of mental health difficulties, this can increase their risk of mortality following a diagnosis (Klassen et al., 2019).

Further work by Boundouki et al., (2019) compared research priorities for breast cancer between patients and general public and healthcare to explore whether there were any differences in what they felt should be prioritised. The top research priorities identified

included loneliness and fear of death, anxiety, fear of cancer recurrence, support following treatment and family relationship dynamics. They also identified a clear need for improved dissemination of information and education relating to breast cancer at all parts of the journey from signs and symptoms to death and dying. There was also a strong focus on quality of life, specifically looking at the side effects of surgery. These factors are also supported in an earlier systematic review by Jarett et al., (2013) who synthesized the work of 16 systematic reviews of psychological and social problems faced by cancer survivors. The core themes included depression, anxiety and distress, fear of recurrence, social support, relationships and impact on family, quality of life, coping and needs. All of the factors discussed seem to be consistent in the literature surrounding the psychosocial impact of cancer, or what people with cancer feel should be the research priorities when evaluating the psychosocial impact. This Delphi study aims to explore whether the measures consistently being used to evaluate psychosocial impact, are consistent with the constructs that people with experience of cancer feel are important and relevant.

This study fits well within the underpinning theory of this thesis whereby people are considered to be experts of their own health. Leventhal (1980) described individuals as common sense scientists, meaning they are the best people to appraise their responses to stressful situations. The Delphi method utilises 'experts' within a particular area or field but the term expert in this scenario can be whatever parameters are set by the researcher. The type of experts will depend on the research aims and objectives, which the following section will go on to detail. This phase of the research falls within the preparation phase, which aligns with the MRC framework (Skivington, 2021), where it taps into the core elements of engaging stakeholders and identifying key priorities.

Aim & objectives

The primary aim of this study was to engage cancer experts in an online Delphi study to explore consensus on which key health constructs are considered the most important and

relevant to measure when evaluating the impact of a cancer support intervention. Embracing the principles of participatory action research (PAR) and patient and public involvement (PPI) the study specifically sought individuals with lived experience of cancer as well as clinical experts, academics and researchers who work the cancer field.

The specific objectives were to:

1. Establish which psychosocial constructs experts consider to be important and relevant to measure when evaluating the psychosocial impact of a cancer support service
2. Explore the importance and relevance of practical issues associated with conducting research as informed by the MRC framework (Skivington, 2021) for evaluating complex interventions

Method

This study used an *Online Modified Delphi* (OMD; Khodyajov et al., 2016) approach to explore consensus amongst cancer experts. The content of the questionnaire was informed by the results of a systematic literature review conducted to identify existing psychosocial outcome measures. Full ethical approval for this study was granted by UTWSD ethics committee on 17/09/2018 (see Appendix A for ethics and Appendix B for study materials)

Participants

A vital element of using the Delphi method is the consideration of 'expert' panel members whilst also considering the importance of patient and public involvement (PPI). Following guidance from Williams, Sansoni, Morris and Thompson (2016), participants were made up of four categories to create the expert panel. These included: healthcare professional, consumer (patient), consumer (carer) and academic or technical expert.

Eligibility criteria for this study stated that an individual should have a personal or professional connection to cancer; meaning they should either have had cancer now or in the past, be supporting a family member or friend with cancer, working as a professional in the cancer field or volunteering with a cancer charity or organisation. These examples were given to clearly explain what was considered 'expert' experience and avoid any confusion over the use of that term. See Appendix B for study materials.

Participants were recruited via social media which ones and Tenovus Cancer Care's quarterly electronic newsletter, which is emailed directly to subscribers, using a carefully created study advert. The study advert went through multiple changes based on feedback from the research team at Tenovus, they were best placed to assess the suitability of the language given that it would be sent out to individuals affected by cancer. This advert was then disseminated on Social media channels which primarily included Twitter with the information for the study being shared directly from Tenovus's Research Team, the Psychology team at UWTSD and personal accounts. The same information was shared on the Psychology team's Facebook page and personal Facebook profiles. Please see Appendix B for study materials.

Design

A two round OMD approach was employed for this study. By using an OMD, this study differed from that of a standard Delphi due to being delivered electronically and the questionnaire used for round one was informed by a systematic literature review. By using an OMD (Figure 11), the key principles of the Delphi technique could be adhered to by allowing anonymity amongst participants; is time and cost effective, ability reach a larger geographical scale and remove the potential for group conflict or domination. All of these elements are considered important for the successful delivery of the Delphi method (Iqbal & Pipon-Young, 2009). Developing the questionnaire went through a series of feedback processes. Following the outcome of the systematic literature review, the psychosocial??

health constructs being measured within the validated scales were extracted and put into categories. These included psychological and emotional functioning, support and needs, physical symptoms and practical aspects. Two further questions were added in which were based on the Medical Research Council (MRC) framework for evaluating complex interventions (MRC, 2000) as this was the up to date framework at the time of data collection. Due to the nature of the PhD research as a whole it felt appropriate to include these questions which related to the practicalities of developing and evaluating interventions. Questions were designed to explore the extent to which participants felt each item to be important and relevant to measure when evaluating the impact of a cancer support service.

Using OMD guidelines to inform the process (Iqbal & Pipon-Young., 2009; Khodyakov et al., 2016; Avella., 2016), following the initial development of the questionnaire, expert feedback was sought from psychology professionals at UWTSD, a secondary breast cancer nurse, and an ex cancer nurse. These individuals were recruited by email and asked to read through and comment on; the information sheet, consent process, expert status categories, the structure and content of the questions and the smooth running of the online Qualtrics system. The questionnaire was also continuously piloted amongst lay individuals with no connection to cancer or academic studies to ensure that the wording of the questions was easy to understand and follow, and that the Qualtrics system was set up correctly. Each piece of feedback was carefully considered and once agreed with the project supervisor was implemented into the questionnaire and Qualtrics system. Please see Table 8. for a summary of the feedback given in the early stages of questionnaire development. Other general feedback was around the use of ‘importance’ and ‘relevance’ as defining terminology within the Delphi questions. It was questioned whether these terms actually differed from one another and how they could be defined within their own right, to allow individuals to rate items based on each of these terms. To start with there was a

definition of each term included at the beginning of the online questionnaire. However, following the feedback process and further project supervision meetings, it was decided to remove the definitions and instead phrase the questions so as an example was included. The change of wording alongside a new star-based rating system seem to make it much clearer and easier to rate on a scale of importance and relevance for each construct. The final questionnaire included 17 questions, using a star-based rating system for questions about relevance and importance and free text boxes for additional qualitative data. The full questionnaire can be found in appendix B.

Data analysis for Delphi studies can vary according to the type of approach used (Powell, 2003). Typically, content analysis techniques are used to identify major themes generated by the initial unstructured questionnaire, and this then informs the basis of the following rounds. For an OMD a different approach is taken to fit the circumstances, so by using the systematic review results and thorough feedback process this replaces the need for an open-ended questionnaire and allows consensus to begin.

For this study consensus was sought on the importance and relevance of the role of key health constructs when evaluating a cancer support intervention. Consensus on an item was considered reached when agreement was 70% and above (Williams et al., 2018). This study used a star-based Likert scale where participants rated each item on its level of importance and relevance from zero to five stars with the option of half increments. This was decided to allow more meaning to be given to items which were more important and relevant than others and to encourage participants to rank items based on their previous answers. Using the combined guidance for analysing a Delphi study and deciding on consensus, the following measurements are reported in this study:

- Mean ratings and standard deviation
- % of agreement amongst respondents
- Ranking of items

- Free text data (items which experts feel were not represented)

Items which are rated very low (< 3) and reach a consensus of 70% and above are removed for the development of the questionnaire for round two, so as to allow the other items to be rated further and agreement reached, following the same analysis and summary feedback.

Table 8

Feedback from expert reviewers and actions taken

Reviewer	Feedback	Actions
Psychology	- Clarity on the information sheet about who the research was for, taking part twice and defining experts - Move criteria for taking part to consent form to remind Ps - Add in progress bar - Some grammatical errors	- Changes made regarding clarity and spelling errors - Consent form changed to include expert status to remind participants of eligibility
Psychology	- Information sheet too long/wordy and could be streamlined to be clearer	- Revised where possible
Psychology	- Clarity on relevance and importance - Less formality on the questions	- Added a definition and example for both before each section of questions as a reminder - Wording of questions was changed to be more lay
Counselling	- Face to face feedback trialling different rating systems for the relevant and important questions.	- Agreed to change to a star-based system, based on previous feedback from DH
Cancer Nurse Specialist	- Rating system is difficult to judge - Clarity needed for 'relevance'	- Star based system introduced to allow participants to rate 0-5 stars with half increments - Definitions given for relevance and importance
Cancer Nurse Specialist	- No issues. Clear instructions and nothing offensive or confusing.	

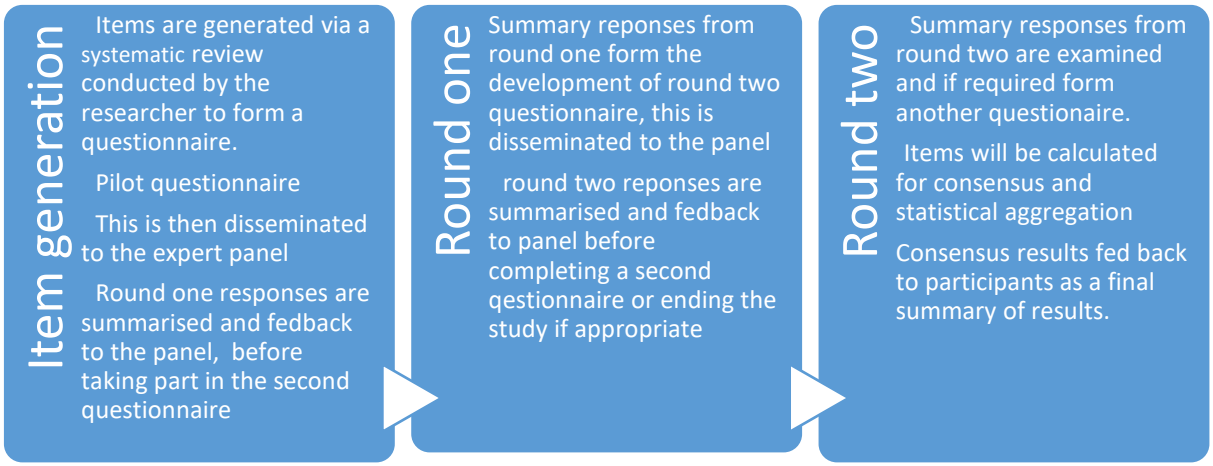
Materials

The online modified Delphi (OMD) was delivered through Qualtrics online survey platform which was used to facilitate the process of delivering questionnaires and controlled feedback to participants, this ensured maximum ease of use as it is optimised for use on computers, mobile devices and handheld tablets (O'Neill et al., 2018). See appendix B for study materials.

Procedure

Figure 11

A visual representation of the OMD process



Round One

Participants were recruited for a period of four weeks and were asked to commit to taking part in two questionnaires which would be completed four to six weeks apart, with feedback iteration built in, data collection lasted for three-month period. Participants were asked to read through the study information sheet and decide whether or not to take part. The consent process for this study included the request for contact details in the form of an email address, to allow for feedback summaries and subsequent questionnaires to be sent to the same participants. To begin participants were asked to select which expert category best represented their experience of cancer. They were presented with five categories, and they could select more than one if appropriate. Categories were made up of the following options: experienced cancer personally, supported a family member or friend with cancer, medical professional working in the cancer field, volunteer with a cancer charity or third sector organisation, or work in cancer research or in a university or college and teach about cancer. The questions were split into five categories: psychological and emotional functioning, support and needs, physical symptoms, practical issues and frequency of

evaluation. Within these five categories, individuals were asked to rate 35 items on their importance and relevance using a 5-point scale. The questionnaire also included the opportunity for free text entry after each group of items within a category had been rated, to account for anything individuals feel may have been missed and should be considered for round two. Following the completion of this questionnaire, participants were provided with a debrief form which explained the next step of the study (see appendix B). Following analysis of round one, items were removed and round two questionnaire was constructed. This process is detailed further in the results section of this chapter. Once completed, this information was displayed in easy to read, colourful tables and feedback to participants prior to completing round two questionnaire.

Round two

Participants who consented and provided an email address at round one, were then emailed the round two questionnaire. This questionnaire began with showing the summary of what had been found in round one. The way this was displayed on Qualtrics ensured participants would see it before completing the second questionnaire. Round two questionnaire was set up in exactly the same way as round one, with a few items having been removed and some added based on the free text data from round one. This is explained in more detail in the results section below. Round two asked participants to rate items again based on a 5-point scale whilst considering the answers they gave in round one. Following the end of this questionnaire, results were analysed and feedback to participants as a final study summary.

Results

Round one

There was a total of 81 respondents to the first round of the online survey over a period of four weeks. Data was downloaded from Qualtrics into SPSS and screened for incomplete cases. There were 48 complete cases (89-100% included) and 33 cases were removed for incomplete data. The final participants for round one included six males and 42 females, the expert categories are shown in Table 9, below. Noting that individuals were able to select more than one option to best represent their expert experience, but it shows that a large proportion of the individuals who took part had experienced cancer themselves as well as another expert role.

Table 9

Proportion of people in each expert category

Expert category	Round one N (%)	Round two
Have personally experienced cancer themselves	33	15
Supported a family member or friend with cancer	17	5
Medical professional working in the cancer field	8	1
Volunteer with charity/third sector cancer organisation	7	1
Work in cancer research	2	2
Work in college or university and teach about cancer	0	0
Total		

Tables 10 to 22 present the findings from the first round of the online modified Delphi study and are broken down into construct categories showing percentage of response for relevance and importance. Participants rated each construct on a five-star Likert system, where 0= no importance or relevance and 5= greatest importance or relevance. As anticipated, there were very few items which were rated very low or zero by a large percentage of participants, however by using the star-based system it gave a better judgement

for the range of importance and relevance for each item. This allowed the items to be ordered from highest to lowest in terms of importance and relevance and subsequently form a summary for participants and construct the questionnaire for round two.

Table 10

Psychological and emotional functioning – relevance

	% Relevance												
Construct	**0**	**0.5**	**1**	**1.5**	**2**	**2.5**	**3**	**3.5**	**4**	**4.5**	**5**	**M**	**SD**
Anxiety	0	2.1	0	0	0	0	2.1	2.1	14.6	8.3	70.8	**4.64**	**.77**
Stress	0	4.2	0	0	0	2.1	4.2	0	14.6	10.4	64.6	**4.47**	**1.03**
PTS	2.1	4.2	0	2.1	4.2	8.3	4.2	4.2	10.4	6.3	54.2	**4.02**	**1.40**
Depression	2.1	0	0	0	4.2	2.1	4.2	4.2	18.8	6.3	58.3	**4.36**	**1.00**
Mood state	2.1	0	0	0	0	2.1	8.3	2.1	16.7	6.3	62.5	**4.45**	**.91**
Worry	0	2.1	0	0	0	4.2	2.1	0	20.8	10.4	60.4	**4.50**	**.87**
Fear	0	2.1	0	0	0	0	8.3	4.2	10.4	4.2	70.8	**4.55**	**.88**
Hope	0	2.1	0	0	0	2.1	6.3	2.1	10.4	8.3	68.8	**4.55**	**.88**
Coping	0	0	0	0	0	0	2.1	2.1	10.4	6.3	77.1	**4.69**	**.77**
Optimism	0	2.1	0	0	2.1	4.2	12.5	2.1	16.7	0	60.4	**4.29**	**1.05**
Acceptance	0	4.2	0	0	0	4.2	8.3	4.2	14.6	2.1	62.5	**4.32**	**1.11**
Distress	0	4.2	0	0	0	6.3	10.4	2.1	14.6	10.4	52.1	**4.21**	**1.13**

This table shows the percentage of consensus about the relevance of each of the constructs within the psychological and emotional functioning category. There is a wide variation in results, with coping and anxiety scoring the highest relevance for the most amount of people. Post-traumatic stress (PTS) had the biggest variation in response with it being the only construct that had a response for each possible star. Looking at the mean scores, PTS also comes out as the lowest rated item within this category, although still scoring above 4 so still deemed relevant. PTS follows stress in the list of constructs displayed in the questionnaire and it is interesting to see that it elicited different responses from participants as it was thought that this may cause some confusion.

Table 11

Psychological and emotional functioning - importance

	% Importance												
Construct	**0**	**0.5**	**1**	**1.5**	**2**	**2.5**	**3**	**3.5**	**4**	**4.5**	**5**	**M**	**SD**
Anxiety	0	0	2.1	0	0	4.2	10.4	0	10.4	6.3	66.7	**4.46**	**.93**
Stress	0	2.1	6.3	0	2.1	6.3	12.5	6.3	18.8	0	45.8	**3.90**	**1.29**
PTS	2.1	10.4	4.2	2.1	8.3	2.1	10.4	8.3	10.4	0	41.7	**3.44**	**1.67**
Depression	0	2.1	0	2.1	4.2	16.7	10.4	4.2	18.8	2.1	39.6	**3.82**	**1.20**
Mood state	0	0	0	2.1	6.3	12.5	8.3	6.3	22.9	4.2	37.5	**3.91**	**1.07**
Worry	0	2.1	4.2	0	4.2	4.2	8.3	4.2	27.1	8.3	37.5	**3.96**	**1.18**
Fear	0	0	0	6.3	8.3	8.3	10.4	8.3	6.3	10.4	41.7	**3.87**	**1.22**
Hope	0	2.1	2.1	2.1	2.1	2.1	18.8	6.3	20.8	4.2	39.6	**3.93**	**1.15**
Coping	0	0	0	0	4.2	2.1	2.1	8.3	18.8	10.4	52.1	**4.32**	**.98**
Optimism	0	2.1	2.1	2.1	12.5	2.1	6.3	18.8	22.9	4.2	27.1	**3.66**	**1.19**
Acceptance	0	0	2.1	6.3	8.3	10.4	10.4	4.2	18.8	2.1	37.5	**3.71**	**1.26**
Distress	0	4.2	0	2.1	6.3	4.2	12.5	4.2	22.9	6.3	37.5	**3.87**	**1.23**

Table 11 shows the percentage of consensus about the importance of each of the constructs within the psychological and emotional functioning category. Mean scores of all items are lower than that from the relevance table, although anxiety and coping remain the highest rated with the most consensus. This could suggest that overall, these items are considered more relevant than important, and suggests that participants were able to distinguish between the two. There is more variation in lower scores for importance especially for depression, distress, worry, hope and optimism. Again, PTS has the lowest mean score falling just under 3.5 stars.

Table 12

Free text data and associated action for round two

Free text	**Actions**
Anger	Add to R2
Family	Add to R2
Grief	Add to R2
Understanding	Add to R2

Table 13

Support and needs - relevance

	% Relevance												
Construct	**0**	**0.5**	**1**	**1.5**	**2**	**2.5**	**3**	**3.5**	**4**	**4.5**	**5**	**M**	**SD**
Maintaining relationships	0	0	2.1	0	0	0	18.8	8.3	14.6	2.1	54.2	**4.26**	**.94**
Maintaining Friendships	0	0	2.1	0	2.1	2.1	16.7	12.5	18.8	6.3	39.6	**4.06**	**.97**
Social support	0	0	0	2.1	2.1	2.1	16.7	6.3	27.1	4.2	39.6	**4.09**	**.92**
unmet needs	0	0	0	2.1	8.3	2.1	12.5	8.3	16.7	6.3	43.8	**4.05**	**1.06**
Loneliness	0	0	2.1	0	8.3	2.1	14.6	6.3	16.7	8.3	41.7	**4.02**	**1.09**
Isolation	0	0	0	0	8.3	0	10.4	6.3	18.8	2.1	54.2	**4.25**	**.97**
Financial concern	0	0	2.1	0	0	0	6.3	6.3	20.8	4.2	60.4	**4.46**	**.82**
Support following treatment	0	0	2.1	0	0	0	6.3	2.1	10.4	10.4	68.8	**4.60**	**.78**
Spiritual needs	2.1	8.3	14.6	2.1	8.3	4.2	16.7	8.3	16.7	4.2	14.6	**2.86**	**1.52**

Table 13 shows the percentage of consensus about the relevance of each of the constructs within the support and needs category. From the mean scores alone, it shows that asking about support following treatment is the highest rated with the most consensus on scores between four and five stars. Spiritual needs has the lowest mean score, with consensus

split across the rating options with slightly more consensus showing for rating three stars and under (53%). Asking about maintaining friendships, social support, unmet needs and loneliness were all rated around the same scores. Scores for loneliness are slightly lower than that for isolation, suggesting that participants were able to distinguish levels of relevance between the two items.

Table 14

Support and needs - Importance

	% Importance												
Construct	**0**	**0.5**	**1**	**1.5**	**2**	**2.5**	**3**	**3.5**	**4**	**4.5**	**5**	**m**	**SD**
Maintaining relationships	0	2.1	4.2	2.1	2.1	8.3	14.6	2.1	16.7	2.1	45.8	**3.89**	**1.29**
Maintaining Friendships	0	2.1	2.1	4.2	2.1	8.3	18.8	6.3	25	4.2	27.1	**3.66**	**1.17**
Social support	0	0	2.1	2.1	2.1	8.3	20.8	10.4	12.5	12.5	29.2	**3.81**	**1.06**
Unmet needs	0	0	4.2	8.3	2.1	6.3	16.7	10.4	10.4	4.2	37.5	**3.70**	**1.28**
Loneliness	0	0	2.1	4.2	6.3	6.3	12.5	10.4	20.8	2.1	35.4	**3.80**	**1.15**
Isolation	0	0	2.1	0	8.3	2.1	8.3	12.5	22.9	4.2	39.6	**4.01**	**1.05**
Financial concern	0	0	2.1	0	2.1	0	14.6	6.3	16.7	0	58.3	**4.30**	**.97**
Support following treatment	0	0	0	0	2.1	4.2	8.3	0	14.6	10.4	60.4	**4.46**	**.82**
Spiritual needs	0	14.6	18.8	6.3	10.4	6.3	12.5	8.3	6.3	2.1	14.6	**2.45**	**1.54**

Table 14 shows the percentage of consensus about the importance of each of the constructs within the support and needs category. Overall, the mean scores are generally lower than in the relevance table. The highest rated item is support following treatment, and the lowest is spiritual needs, so although mean scores are lower, both of these constructs remain as the most and least important/relevant in this round. Excluding spiritual needs, there are no other constructs which fall under a mean score of 3.5 stars, however there are none that have a mean score above 4.5 stars.

Table 15

Free text

Free text	**Actions**
Body image	Add to R2

Table 16

Physical symptoms - Relevance

	% Relevance												
Construct	**0**	**0.5**	**1**	**1.5**	**2**	**2.5**	**3**	**3.5**	**4**	**4.5**	**5**	**M**	**SD**
Pain	0	0	2.1	0	2.1	0	6.3	10.4	6.3	2.1	70.8	**4.50**	**.91**
Discomfort	0	0	2.1	2.1	2.1	2.1	12.5	4.2	20.8	4.2	50	**4.18**	**1.03**
Symptom progression	0	0	2.1	2.1	2.1	2.1	4.2	8.3	12.5	4.2	62.5	**4.37**	**1.01**
Energy levels	0	0	0	0	6.3	2.1	6.3	6.3	20.8	6.3	52.1	**4.30**	**.91**
Sleep hygiene	0	2.1	0	0	4.2	2.1	10.4	4.2	20.8	2.1	54.2	**4.23**	**1.04**
Appetite	0	4.2	0	0	6.3	4.2	25	6.3	14.6	2.1	37.5	**3.77**	**1.21**

Table 16 shows the percentage of consensus about the relevance of each of the constructs within the physical symptoms category. Although the main focus of the PhD is psychosocial evaluation, it was felt important to address the physical symptoms associated with cancer, as many of the measures that emerged from the review, included physical symptoms in some way. The highest rated item with the most consensus is pain, with the lowest being appetite. Pain, discomfort and symptom progression all had some consensus for ratings under two stars, however higher consensus on four and five stars which raised the overall mean score.

Table 17

Physical symptoms - Importance

	% importance												
Construct	**0**	**0.5**	**1**	**1.5**	**2**	**2.5**	**3**	**3.5**	**4**	**4.5**	**5**	**M**	**SD**
Pain	0	0	2.1	2.1	0	0	4.2	4.2	12.5	8.3	66.7	**4.53**	**.88**
Discomfort	0	0	2.1	0	4.2	0	8.3	12.5	35.4	6.3	31.3	**4.05**	**.90**
Symptom progression	0	0	2.1	0	6.3	6.3	4.2	2.1	18.8	4.2	56.3	**4.25**	**1.07**
Energy levels	0	0	0	4.2	2.1	10.4	18.8	8.3	20.8	0	35.4	**3.82**	**1.06**
Sleep hygiene	0	4.2	0	0	10.4	4.2	20.8	6.3	16.7	4.2	33.3	**3.69**	**1.23**
Appetite	0	2.1	4.2	6.3	14.6	4.2	14.6	8.3	14.6	4.2	27.1	**3.39**	**1.34**

Table 17 shows the percentage of consensus about the importance of each of the constructs within physical symptoms category. Scores on importance are similar to those in the relevance table, with slightly lower mean scores for importance. The highest rated item was pain and the lowest was appetite, so this stayed the same for both relevance and importance.

Table 18

Physical symptoms - Free text

Free text	**Actions**
Body image	Added to R2
Mental health	None
Support during chemotherapy/support with all above constructs	None
Mental strength	None
Nausea Constipation Diarrhoea	None
Provision of relevant information	None
Sexuality	Added to R2
Side effects of treatment: menopause, bowel & bladder symptoms, sexual dysfunction	None

Table 19

Practical issues - Relevance

	% Relevance												
Construct	**0**	**0.5**	**1**	**1.5**	**2**	**2.5**	**3**	**3.5**	**4**	**4.5**	**5**	**M**	**SD**
Easy to use	0	0	2.1	0	4.2	0	6.3	0	16.7	0	70.8	4.50	.94
Easy to access	0	0	4.2	0	2.1	0	2.1	0	10.4	0	81.3	4.62	.95
Value for money	0	0	10.4	0	10.4	0	29.2	0	22.9	0	27.1	3.45	1.28
Efficiency	0	0	4.2	0	6.3	0	8.3	0	39.6	0	41.7	4.08	1.06
Clear instructions	0	0	6.3	0	6.3	0	12.5	0	27.1	0	47.9	4.04	1.20
Time involved	0	0	6.3	0	8.3	0	25	0	37.5	0	22.9	3.62	1.12
Opportunity for feedback	0	0	8.3	0	10.4	0	25	0	27.1	0	29.2	3.58	1.25
Clear purpose	0	0	4.2	0	0	0	12.5	0	29.2	0	54.2	4.29	.98

Table 19 shows the percentage of consensus about the relevance of each of the constructs within the practical aspects category. This category differed with it being more related to how the intervention or support service is developed and delivered. The most relevant item here being easy to access and the least relevant being value for money. This is interesting because people may not consider a services value for money, especially if that service is being provided for free.

Table 20

Practical issues - Importance

	% importance												
Construct	**0**	**0.5**	**1**	**1.5**	**2**	**2.5**	**3**	**3.5**	**4**	**4.5**	**5**	**M**	**SD**
Easy to use	0	0	8.3	0	2.1	0	2.1	0	16.7	0	70.8	**4.39**	**1.19**
Easy to access	0	0	2.1	0	4.2	0	2.1	0	16.7	0	75	**4.58**	**.89**
Value for money	0	0	10.4	0	18.8	0	20.8	0	22.9	0	27.1	**3.37**	**1.34**
Efficiency	0	0	8.3	0	4.2	0	14.6	0	33.3	0	39.6	**3.91**	**1.21**
Clear instructions	0	0	10.4	0	0	0	20.8	0	33.3	0	35.4	**3.83**	**1.22**
Time involved	0	0	18.8	0	6.3	0	25	0	29.2	0	20.8	**3.27**	**1.37**
Opportunity for feedback	0	0	10.4	0	18.8	0	27.1	0	14.6	0	29.2	**3.33**	**1.35**
Clear purpose	0	0	2.1	0	2.1	0	14.6	0	22.9	0	58.3	**4.33**	**.95**

Table 20 shows the percentage of consensus about the importance of each of the constructs within the practical aspects category. There is very little difference between the mean scores in this table when compared to the results reported for relevance in Table 19, with the highest rated item for importance being easy to access and the lowest being time involved. Consensus is low for items rated 4 and 5 when compared to the other categories, with much more variation in lower scores.

Table 21

Practical issues - Free text

Free text	**Actions**
Availability (hours outside normal working hours)	Add to R2
Outcomes	None
Taking into account everyone's varying ability for things such as technology or research	None

Frequency of evaluating impact

Table 22

Percentage of participants who responded to each option

	ONCE (AFTER SERVICE)	BEFORE & AFTER	WITHIN 6 MONTHS	WITHIN 12 MONTHS	LONGER THAN 12 MONTHS	OTHER
% SELECTED	2.1	77.1	45.8	25	14.6	8.3

Table 20 shows the percentage of consensus on each option for how often an individual should be asked about the various constructs contained within the categories. It was explained in the question that this is to allow the impact of the service to be evaluated based on the constructs previously mentioned and participants could select more than one option. There was greater consensus for 'before and immediately after using a service' and also good consensus for 'within six months of using a service. Asking individuals once was rated the lowest, which is fairly consistent with the literature as this is unlikely to tell us much about the impact of a service. It was felt that this was an adequate enough response for this question and was not asked again in round two.

Table 23

Other – free text

'Other' Free text	**Actions**
As you go along	None
Before & immediately after and 6 months later	None
During service use	None
As long as people consent, they should be monitored and checked in on monthly or weekly if they need it/are more vulnerable	None

Summary

Overall, the results for round one showed high ratings for importance and relevance for most items. Items were generally rated more relevant than important in all categories and those which were the most and least relevant or important respectively, stayed the same in each category. The results of round one were summarised and used to construct the development of the questionnaire for round two, both of which were emailed to participants who provided their email address at the start of the study.

Round two

Round two questionnaire was sent to a total of 48 participants and 19 of those completed the questionnaire. The study was open for four weeks and two reminders were sent to participants (as previously agreed at the start of the study). Data was downloaded from Qualtrics into SPSS and screened for incomplete cases. The final participants for round two included two males and 17 females with a mean age of 46.1 (*SD*=13.1), the expert categories are shown in Table 22 below. Noting that individuals were again able to select more than one option to best represent their expert experience, but it shows that a large proportion of the individuals who took part had experienced cancer themselves as well as another expert role, which is an interesting finding considering the project is trying to develop a tool to best benefit those who have experienced cancer.

Table 24

Expert status categories for round two

Expert category	Response
Have personally experienced cancer themselves	15
Supported a family member or friend with cancer	5
Medical professional working in the cancer field	1
Volunteer with charity/third sector cancer organisation	1
Work in cancer research	2
Work in college or university and teach about cancer	0

Tables 25 to 38 present data from round one and two combined. The first table for each category shows that consensus has been summarised to conclude the percentage of people who rated an item low (≤3.5) and high (≥4). The second table shows mean ratings of each construct in round one and two and the change between the two, whether this increased or decreased.

Table 25

Percentage of consensus for psychological and emotional functioning in round one and two

	ROUND ONE CONSENSUS					ROUND TWO CONSENSUS			
	RELEVANCE		IMPORTANCE			RELEVANCE		IMPORTANCE	
CONSTRUCTS	*≥4*	*≤3.5*	*≥4*	*≤3.5*		*≥4*	*≤3.5*	*≥4*	*≤3.5*
Acceptance	79%	21%	58%	42%		86%	14%	57%	43%
Anxiety	94%	6%	83%	17%		100%	0%	86%	14%
Coping	94%	4%	81%	17%		100%	0%	100%	0%
Depression	83%	17%	60%	40%		86%	14%	57%	43%
Distress	77%	23%	67%	33%		64%	36%	57%	43%
Fear	85%	15%	58%	42%		86%	14%	71%	29%
Hope	88%	12%	65%	35%		79%	21%	71%	29%
Mood state	86%	14%	65%	35%		93%	7%	57%	43%
Optimism	77%	23%	54%	46%		57%	43%	57%	43%
PTS	71%	29%	52%	48%		57%	43%	43%	57%
Stress	90%	10%	65%	35%		93%	7%	71%	29%
Worry	92%	8%	73%	27%		93%	7%	72%	29%
					Anger	71%	29%	36%	64%
					Body Image	79%	21%	71%	29%

Table 25 above shows the items that reached consensus highlighted in green and those just below highlighted in yellow. All items within this category reached consensus for relevance in round one, with stress, anxiety, coping and worry all reaching above 90% consensus for highly relevant. Anxiety, coping and worry also reached consensus on being highly important in round one, with the majority of the other items not quite reaching 70% however, over half the participants agreed they were important. Levels of consensus increased for high importance for fear, hope and stress taking them over 70%. Items such as coping reached 100% consensus for both relevance and importance in both rounds. Items such as fear, hope, depression, stress, worry and body image were consistently rated very important and relevant by over 70% of participants in both rounds. Body image and anger were items added into round two following feedback from round one. An interesting finding for anger was that it was rated highly relevant by over 70% of participants but was rated very low in importance by 64%. Overall, the items in this category were all deemed highly relevant but slightly less important with consensus increasing in round two.

Table 26

Mean scores for constructs within psychological and emotional functioning, showing change between rounds one and two

	Relevance		Importance		Relevance	Importance
Construct	**R1**	**R2**	**R1**	**R2**	**R2 Change**	**R2 Change**
Acceptance	4.32	4.14	3.71	3.67	-0.18	-0.43
Anxiety	4.64	4.67	4.46	4.53	0.03	-0.21
Coping	4.69	4.82	4.32	4.75	0.13	-0.5
Depression	4.36	4.21	3.82	3.14	-0.15	-0.39
Distress	4.21	4	3.87	3.75	-0.21	-0.13
Fear	4.55	4.5	3.87	4.32	-0.05	-0.63
Hope	4.55	4.25	3.93	3.89	-0.3	-0.32
Mood State	4.45	4.57	3.91	4	0.12	-0.66
Optimism	4.29	3.85	3.66	3.78	-0.44	-0.19
PTS	4.02	3.64	3.44	3.14	-0.38	-0.2

Stress	4.47	4.67	3.9	4.21	0.2	-0.77
Worry	4.5	4.57	3.96	4.17	0.07	-0.61
Body Image	.	4.39	.	4		
Anger	.	4	.	3.21		

Social support and needs

Table 27

Percentage of consensus of functioning in round one and two

	ROUND ONE CONSENSUS					ROUND TWO CONSENSUS			
	RELEVANCE		IMPORTANCE			RELEVANCE		IMPORTANCE	
CONSTRUCTS	≥4	≤3.5	≥4	≤3.5		≥4	≤3.5	≥4	≤3.5
Financial concern	85%	15%	75%	25%		86%	14%	86%	14%
isolation	75%	25%	67%	33%		93%	7%	79%	21%
Loneliness	67%	33%	58%	42%		71%	29%	79%	21%
Maintaining Friendships	65%	35%	56%	44%		86%	14%	86%	14%
Maintaining relationships	71%	29%	65%	35%		50%	50%	57%	43%
Social support	71%	29%	54%	46%		64%	36%	64%	36%
Spiritual needs	35%	65%	23%	77%		.	.	.	.
Support following treatment	90%	10%	85%	15%		93%	7%	93%	7%
Unmet needs	67%	33%	52%	48%		43%	57%	73%	29%
					Family	64%	36%	57%	43%
					Grief	50%	50%	50%	50%
					Sexuality	43%	57%	29%	71%
					Understanding	71%	29%	79%	21%

Table 27 above shows the level of consensus for each construct in the social support and needs category. Financial concern, isolation, maintaining relationships, social support and support following treatment all reached consensus for highly relevant in round one and increased further in round two. Items such as loneliness and maintaining friendships both increased in consensus for high relevance and importance in round two. There were four

new items added to this category following feedback from round one, family, grief, sexuality and understanding. The results for these items are quite mixed, only understanding reached consensus on being highly relevance and important. Sexuality was deemed of little importance by over 70% of people with a slightly higher percentage rating it less relevant also. Spiritual needs were removed for round two due to it being rated very low in round one by over 70% of people. Overall, this was a mixed category for levels of relevance and importance, with financial concern, isolation, maintaining friendships, support following treatment and understanding being reported as the most important and relevant items.

Physical symptoms

Table 28

Percentage of consensus for physical symptoms in rounds one and two

	ROUND ONE CONSENSUS					ROUND TWO CONSENSUS			
	RELEVANCE		IMPORTANCE			RELEVANCE		IMPORTANCE	
CONSTRUCTS	≥4	≤3.5	≥4	≤3.5		≥4	≤3.5	≥4	≤3.5
Appetite	54%	46%	46%	54%		64%	36%	57%	43%
Discomfort	75%	25%	73%	27%		64%	36%	50%	50%
Energy Levels	79%	21%	56%	44%		86%	14%	93%	7%
Pain	79%	21%	87%	13%		79%	21%	79%	21%
Sleep hygiene	77%	23%	54%	46%		72%	29%	93%	7%
Symptom Progression	79%	21%	79%	21%		93%	7%	86%	14%
					Side effects	79%	21%	86%	14%

Table 28 above discusses the levels of consensus for the physical symptoms associated with a cancer diagnosis. Appetite failed to reach consensus in round two, however was rated higher in relevance than importance in round two. Energy levels, pain, sleep hygiene and symptom progression were consistently rated high in round two by over 70% of participants. Side effects was a new item for this category added in following feedback from round one, it was rated high in importance and relevance and reached consensus in

round two. Discomfort had reached consensus for being highly relevant in round one, however the levels decreased in round two. This could be due to the fact that side effects were added and encompasses discomfort when individuals were considering it. Overall, the most important and relevant items within this category were energy levels, pain, sleep hygiene, symptom progression and side effects which all reached consensus.

Table 29

Mean scores for symptoms between round one and two

	Relevance		Importance		Relevance	Importance
Construct	**R1**	**R2**	**R1**	**R2**	**R2 Change**	**R2 Change**
Appetite	3.77	3.92	3.39	3.6429	0.15	-0.53
Discomfort	4.18	3.92	4.05	3.8214	-0.26	0.13
Energy levels	4.3	4.6	3.82	4.5357	0.3	-0.78
Pain	4.5	4.53	4.53	4.5	0.03	0
Sleep hygiene	4.23	4.1	3.69	4.2143	-0.13	-0.41
Symptom progression	4.37	4.6	4.25	4.5	0.23	-0.35
Side effects of treatment	.	4.42	.	4.5714		

Practical issues

Table 30

Percentage of consensus for practical issues in rounds one and two

	ROUND ONE CONSENSUS					ROUND TWO CONSENSUS			
	RELEVANCE		IMPORTANCE			RELEVANCE		IMPORTANCE	
CONSTRUCTS	≥4	≤3.5	≥4	≤3.5		≥4	≤3.5	≥4	≤3.5
Clear instructions	75%	25%	69%	31%		79%	21%	71%	29%
Clear purpose	83%	17%	81%	19%		93%	7%	86%	14%
Easy to access	92%	8%	92%	8%		100%	0%	100%	0%
Easy to use	88%	13%	88%	12%		93%	7%	93%	7%
Efficiency	81%	19%	73%	27%		64%	36%	71%	29%
Opportunity for feedback	56%	44%	44%	56%		72%	29%	64%	36%
Time involved	60%	40%	50%	50%		71%	29%	57%	43%
Value for money	50%	50%	50%	50%		43%	57%	57%	43%
					Availability	93%	7%	93%	7%

Table 30 shows the percentage of consensus for items within the practical issues category. The items with the highest consensus for highly important and relevant are clear

instructions, clear purpose, easy to access and easy to use. Levels of consensus dropped slightly in round two for efficiency, but it was still rated higher in importance and relevance. Value for money was rated low and did not reach consensus, however more than half of participants felt it was lower in relevance and importance than the other items in this category. Availability was a new item that was added in following feedback from round one, it was rated high in importance and relevance and had very high levels of consensus amongst participants. Overall items increased in consensus in round two, with easy to access reporting 100% consensus and most other items reaching consensus on being high in importance and relevance.

Discussion

The purpose of this study was to engage self-defined cancer experts in establishing consensus about which health constructs were the most important and relevant to measure when evaluating the psychosocial impact of a cancer support service. A total of 34 attributes were examined in this study, 26 of these came from validated psychometric scales extracted from a systematic review. A final 24 attributes were considered to be the most important and relevant to consider when evaluating an intervention which can be seen Table 31 below. An item was deemed of high importance or relevance if it was rated ≥4 by over 70% of the participants.

Table 31

List of most important and relevant constructs to measure sorted alphabetically only

Acceptance	Energy levels	Maintaining friendships	Stress
Anger	Fear	Mood state	Support following treatment
Anxiety	Financial concern	Pain	Symptom progression
Body Image	Hope	Side effects of treatment	Understanding
Coping	Isolation	Sleep hygiene	Unmet needs
Depression	Loneliness	Social support	Worry

Priorities for psychosocial cancer research largely focus on anxiety and depression (Niedzwiedz et al., 2019; Pitman et al., 2018; Howell et al., 2013; Walker et al., 2013), and overall quality of life (Boundouki et al., 2019; Jarett et al., 2013). Quality of life is a multifaceted construct and therefore this study did not ask about quality of life as a lone construct, but instead broke it down into the facets that make up quality of life. An example of one of the measures used to demonstrate this is the FACT-G (Cella & Tuskey, 1993). This validated questionnaire seeks to measure quality of life in a general cancer population, some of the constructs that underpin this are acceptance, coping, support, side effects and worry. These constructs were rated highly important and relevant by

individuals, this gives a better understanding of individual priorities than just asking about quality of life in general.

All of the constructs within the psychological and emotional functioning category were considered highly relevant but not all highly important. Within this category anxiety and coping were consistently rated highly in both relevance and importance, which was expected and supported by much of the literature surrounding research priorities. With anxiety being one of the most commonly cited complaints for people affected by cancer. Coping was not measured by an individual questionnaire, but it was incorporated as a construct across four of the validated measures (FACT-G, FCRI, QLQ-C30 & SUNS-SF). People can be defined by how they cope if coping is measured as a whole construct, there are many measures that would classify someone as having a particular type of coping style (emotion-focused, problem-focused etc) but the measures identified in the systematic review which led to this study, did not highlight a coping measure. Finding out how people cope or the types of coping strategies that are used could help better inform the design of future cancer support initiatives.

Many of the worries associated with cancer often focus on the individual during cancer treatment, however it was clear that financial concern, isolation, social support and support following treatment is very important and relevant to measure. This idea is supported by the literature which discusses that a good support system is important throughout the cancer journey to help deal with any concerns such as finances which can often be a problem. It is clear that psychosocial health is also made up of clinical outcomes as almost all of the physical constructs were rated highly important and relevant by participants, and although they are measuring clinical outcomes, it is likely the side effects of these outcomes that impact psychosocial health. For example: poor sleep, pain and energy levels would all contribute to poor psychosocial wellbeing as tiredness and pain have links to feelings of depression.

An interesting finding from this study is that individuals indicated that coping was a construct that was important and relevant to measure. This is interesting given the lack of consensus surrounding the meaning of coping and how to measure it. It would have been insightful to understand how the participants interpreted this construct and how they felt each of these things should be asked. Participants were offered the chance to provide further information following each round of the Delphi, but it was not anchored to a specific construct. This is something that could be done in future, to try and explore interpretation of these constructs, especially with coping. This would help to understand what it means to measure coping or whether it is something that is not measured but demonstrated.

The final constructs identified in Table 31 represent the stress and coping literature and the original constructs within the self-regulation model. Health and emotional outcomes are expected when using this model to understand how people cope with stress or illness. Around 15 constructs represent health and emotional outcomes and the others represent practical outcomes or coping responses. For example, maintaining friendships and support following treatment fit the coping response category rather than a coping outcome.

Strengths and limitations

A total of 48 participants completed round one and only 19 of those completed round two. This drop-out rate was expected and is documented widely in the Delphi literature (Khodyakov et al., 2017; Bains & Regan de Bere, 2018; Kearney et al. 2017). The majority of participants were females (R1 n=33; R2 n=15) and the majority of people had experienced cancer personally (some in addition to another role). This highlights a limitation with the self-defined experts as due to the way in which the information was collected, there was no way of differentiating between those who have/were currently living with cancer and those who were one of the other categories as they could choose

multiple options to define themselves. The expert categories were chosen to try and represent a wide range of opinions within the cancer field. So whilst not being able to do this meant it was a limitation, the data gathered was still considered useful and valuable because the toolkit was designed for people affected by cancer and therefore still represents that population.

The Delphi method is widely criticised for having variations in reporting guidelines (Boulkedid et al., 2011; Diamond et al., 2014) and this was something that was very apparent when trying to plan an online modified Delphi that did not follow the typical guidelines for a standard Delphi. Guidance for conducting modified Delphi studies state that as long as the core principles of a Delphi are achieved (anonymity, multistage iteration, expert panel) and the planning process was documented in depth, that this is sufficient. In-depth documentation is seen as good practice for the methods undertaken (Skulmoski et al., 2007). Anonymity amongst participants was easy to achieve due to conducting the study online using Qualtrics. As there was no need to capture any identifying information or any need for participants to engage with each other, it meant that total anonymity amongst participants was maintained throughout. As mentioned previously, anonymity is an important part of a successful Delphi study, it helps to minimise group conflict and to greater encourage divergence of opinion (Fink et al., 1984; O'Neill et al., 2018). The disadvantage of adhering to the anonymity principle is missing out on the potential for constructive discussion on each of these items. It may have been interesting to hear some discourse between those who have experienced cancer personally and those who work in a research or academic role. This sort of discourse would be best suited to a focus group design; however it would have minimised the other benefits of using the Delphi method such as: reaching a wider audience and being time and cost effective. By delivering the Delphi study online it allowed for an efficient multistage iteration between participants, and they were clearly presented with the group summary

before proceeding to the second round of the survey which is another one of the core principles of a Delphi study (Bains & Regan de Bere, 2018). Participants did not see a summary of their own individual answers before proceeding to round two, so it is possible that they may have forgotten exactly how they rated items in comparison to the group response, however the results did not vary hugely between rounds.

Conclusion

This Delphi study gathered expert consensus on a range of psychosocial health outcomes, which were derived from the systematic review. The results of the systematic review and Delphi combined is the best example of triangulation within this body of work. The result of this meant that a solid number of expert informed constructs and subsequent measurement scales were chosen to create a solid foundation to develop the psychosocial toolkit, the in-depth process of which is documented in the next chapter. The findings in this chapter demonstrate that there are a number of constructs that are more important and relevant to people affected by cancer than the breadth of constructs being measured in the literature. It also supported the use of the Delphi method in exploring consensus in this area and is a method that could be applied to other health conditions to achieve the same outcomes.

There was some discussion around the use of the Delphi study as a method of PPI, despite this not being best practice for PPI it does allow for the psychosocial toolkit to be informed by the target population which fits the gold standard for developing outcome measures. Dewey's (1933) model talks about a process of identifying a problem, reflecting on that problem, actioning the problem and reflecting again like a full cycle. This can be seen through the Delphi process due to the multiple rounds of iteration, providing feedback and responding to that feedback. It was an important element throughout this work that there was a constant cycle of reflection adapting to feedback received in order to strengthen what was being developed.

Chapter Six: Development and User Experience (UX) evaluation of the Tenovus: Psychosocial Outcomes Toolkit (T:POT) and Interface.

This chapter details how the findings from Chapter four and five were triangulated to form the T:POT and the steps involved in the development and piloting of the wider interface drawing on the field of human-computer interaction (HCI). The first section of this chapter details the process of identifying the gold standard measures through the mapping of data from the systematic review (Ch 4) and Delphi (Ch 5). Section two provides a detailed overview of the process of developing the interface that supports the use of T:POT, and Section Three reports on the two UX studies exploring the acceptability of the overall T:POT interface. The work discussed in this chapter falls both within the development and the evaluation phase as outlined in figure 5.

Chapter four (systematic review) and five (Delphi consensus study) directly inform the development of the psychosocial toolkit which will be discussed in this chapter as well as the pilot study conducted to test the efficacy of the toolkit. The previous chapters have discussed the process in which the validated questionnaire measures that make up the toolkit have been identified and this process will be detailed more clearly in this chapter. The previous chapters have also detailed the development and usability evaluation of the human-computer interface (T:POT) that has been developed as part of this PhD research. The T:POT platform hosts the validated questionnaires which form the psychosocial toolkit. One of the aims of this PhD was to develop a gold standard psychosocial evaluation toolkit to evaluate the relative impact of cancer support services.

Creation of the Tenovus: Psychosocial Outcomes Toolkit (T:POT)

Eleven disease specific instruments validated on a cancer population, measuring components of psychosocial health were identified. Articles were specifically sourced which reported on the development of a measure and subsequent validation on a cancer

population. Levels of overall evidence were not reported due to the review focusing on the quality of the development and validation process of the measure in question.

Methodological quality was assessed using the COSMIN checklist, each instrument had ratings given for the measurement properties within it. In order to assess which of these instruments performed better based on the evidence provided in the validation paper, a new scoring system was developed following the use of the COSMIN 'worst score counts' method to give each property an overall rating. Using the COSMIN checklist, measurement properties are given one of four overall ratings; very good (V); Adequate (A); Doubtful (D) and Inadequate (I). By assigning a value to each of these ratings, an overall score for that measure can be produced. However, it is important to highlight where each measure performed exceptionally well regardless of the score. The results section of this chapter discusses each instrument in full and how it performed on each measurement property.

The proposed scoring system would assign a value of zero to four for each measurement rating. For example, very good = 4; adequate = 3; doubtful = 2; inadequate =1 and where the measurement property is not reported, it would receive no score. If each measurement property were to receive a rating of 'very good' then it would achieve a maximum score of 36, therefore each instrument will have a score of X/36. By using this system, the instruments can be ranked, as shown in Table 32

Table 32

Ranking of PROMS

Instrument	Overall score /36	Measurement properties reported and evaluated /9
FACT-G	35/36	9/9
CAYA	25/36	7/9
FCRI	24/36	7/9
HWS	23/36	8/9
QLQ-C30	22/36	7/9
HADS	20/36	6/9
PSCL	20/36	6/9
CONNECS	19/36	6/9
SUNS-SF	16/36	5/9
CNAT	15/36	6/9
CLS	14/36	4/9

From this scoring system seen in Table 32, FACT-G performs marginally better than the other instruments, with some of the other instruments being closer in range. Table 32 shows that the CLS scores the lowest, however it was also the one which had the least amount of measurement properties reported within its validation paper. Eight out of the 11 instruments performed poorly on content validity, with only FACT-G being given a very good rating. The constructs being measured within these instruments all had good Cronbach's α so were all taken forward to be used in the Delphi consensus building study.

Using these constructs a questionnaire was developed for use with people who have experience of cancer, personally or professionally. They were asked to rate each of these constructs on levels of importance and relevance when evaluating the impact of a cancer support service. The results of this study identified the most important and relevant items to measure and combined with the results from the systematic review, can be put together to form a toolkit. Each of the constructs relates to an instrument identified via the systematic review process however not every item within that instrument was considered important or relevant. Additionally, some instruments which rated poorly on the COSMIN checklist, had constructs within it that people considered to be important and relevant to ask about. The table below shows an example of how the results have been combined.

Table 33

Mapping validated measures with Delphi results

Instrument	Overall score /36	Important constructs	Relevant constructs
FACT-G	35/36	Energy Side effects Hope Coping Understanding	Energy Side effects Hope Coping Understanding
CAYA	25/36		
FCRI	24/36	Fear Coping	Fear Coping
HWS	23/36		
QLQ-C30	22/36	Energy levels Pain	Energy levels Pain
HADS	20/36	Anxiety Depression	Anxiety Depression
PSCL	20/36		
CONNECS	19/36		
SUNS-SF	16/36	Financial concern Unmet needs Maintaining friendships	Financial concern Maintaining friendships
CNAT	15/36		Social support
CLS	14/36	Loneliness	Loneliness

This process allowed a final number of four measures to be identified as achieving the aims of both the systematic review and the Delphi consensus study. As seen in Table 33 above, the following measures were identified:

- The *Functional Assessment for Cancer Therapy – General* (FACT-G; Cella & Tuskey, 1993). This is a 33-item questionnaire measuring overall quality of life in a

general cancer population through five subscales including *physical, functional, social, emotional* and *relationship with doctor.* An individual is given a score for each subscale and a total score to indicate overall quality of life

- *Fear of Cancer Recurrence Inventory* (FCRI; Simard & Savard, 2007), a 43-item scale consisting of seven subscales measuring: *triggers, severity, psychological distress, coping strategies, functioning impairments, insight and reassurance*. This scale specifically focuses on the fear associated with a cancer diagnosis returning following treatment.
- *Survivor Unmet Needs Survey – Short form* (SUNS-SF; Campbell et al., 2014), a 30-item scale consisting of four subscales measuring: *information, financial concerns, access and continuity of care* and *relationships and emotional health* which all contribute to the overall measurement of unmet needs in a general cancer population.
- The *Cancer Loneliness Scale* (CLS; Adams et al., 2017) is a 7-item unidimensional scale measuring loneliness following a cancer diagnosis. This scale specifically focuses on how often individuals feel lonely, or isolated at different points of their cancer journey.

In summary, the T:POT is made up of four validated scales, measuring 24 key psychosocial health outcomes. They make up a total of 103 questions and the pilot study reported in chapter seven will detail the length of time it takes to complete the questionnaire and what results it obtains. Table 34 depicts the process of the final measures and how the most important and relevant constructs that were identified in the Delphi study were mapped together to help identify which outcome measures to choose for the final toolkit.

Table 34

A mapping table to show the outcome measures in order of quality and which constructs they measure

Important & Relevant Constructs	FACT-G	CAYA	FCRI	HWS	QLQ-C30	HADS	PSCL	CONNECS	SUNS-SF	CNAT	CLS
Acceptance	X			X							
Anger			X				X			X	
Anxiety			X			X				X	
Body Image		X							X		
Coping	X		X		X				X		
Depression						X			X	X	
Energy levels	X			X	X	X			X	X	
Fear			X						X	X	
Financial concern									X		
Hope	X								X		
Isolation		X								X	X
Loneliness									X	X	X
Maintaining friendships	X								X		X
Mood state							X				
Pain	X	X			X					X	
Side effects of treatment	X				X						

Important & Relevant Constructs	FACT-G	CAYA	FCRI	HWS	QLQ-C30	HADS	PSCL	CONNECS	SUNS-SF	CNAT	CLS
Sleep hygiene	X				X		X			X	
Social support	X									X	X
Stress							X		X		
Support following treatment									X		
Symptom progression	X										
Understanding	X							X			
Unmet needs									X		
Worry	X		X		X	X					

Creation of T:POT Interface

The purpose of developing the T:POT interface was to provide an effective way of conducting psychosocial evaluations of the support services provided by Tenovus Cancer Care and being able to draw comparisons across each service based on a standard set of outcomes. These outcomes were based on the results of the first two phases of the PhD research, consisting of a systematic literature review and a Delphi consensus building study. This section of the development chapter will detail the process that was undertaken to design the interface. The actual coding of the interface prototype was conducted by Vindico who came on board as a collaborator in 2019. The final interface can be accessed via this URL https://tenovus-9e3ab.web.app/ .

In order to test the functionality of the interface, a usability evaluation was conducted. This occurred through three phases (Fig.1), with feedback discussed with Vindico in-between phase one and two. Phase one consisted of a heuristic evaluation with two of the supervisory team who are experts in computing. Phase two piloted online user testing procedures and suitability of the proposed task list with two lay individuals and two colleagues from the Discipline of Psychology and Counselling. Phase three was the final study conducting user testing with four user groups consisting of academics, researchers, patients and Tenovus employees. All three phases were conducted online using Microsoft teams and Zoom, utilising the screen sharing, participant control and recording capabilities.

Initial planning stages with Tenovus

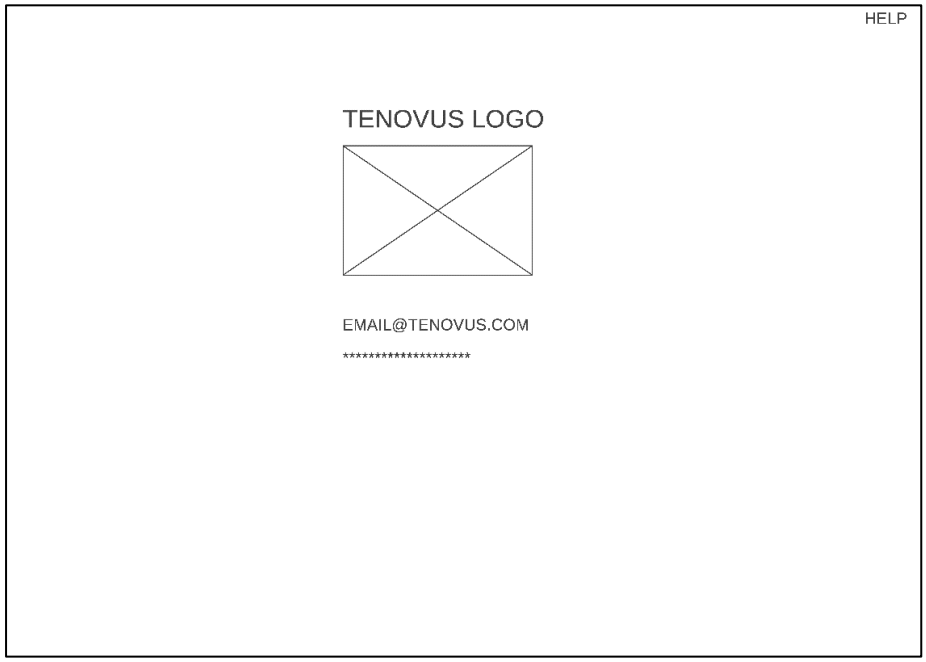
To understand the needs of Tenovus and what may work best for their research team there were many hours spent at head office with various members of staff ranging from heads of service, researchers, admin and the CEO. It was important to establish how they currently evaluated their services, what their expectations were from a product that could assist in the evaluation and how it could be implemented. Following the time spent at

Tenovus, it was important to then meet with the project supervisors from Applied Computing to discuss the findings and how this could be shaped into something tangible that could be developed. It was important to establish what was feasible for a student project in a short space of time but that also best met the needs of Tenovus. The following wireframes were mocked up as the initial ideas came together. Wireframing is a common way to map out a blueprint of a website or development in order to see where things can be structured and how they fit together before the creation of the prototype begins, they are very easy to adapt and are always used at the start of a design phase. These wireframes provided a reference point for discussion with Tenovus in the early stages to determine whether they felt it would meet their expectations.

Wireframes stage one

Figure 12

Sign in page

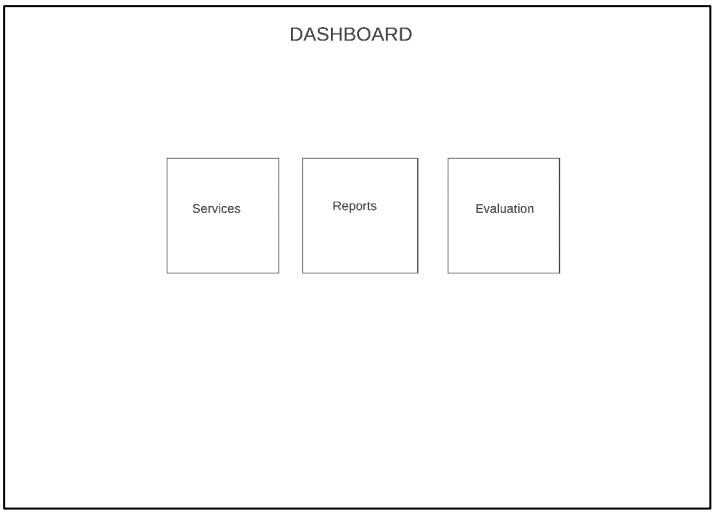


Tenovus take their privacy and security very seriously and therefore it was important that there was a secure and encrypted login process where everyone who would

be using the system would have their own profile and the data being held in the system was protected.

Figure 13

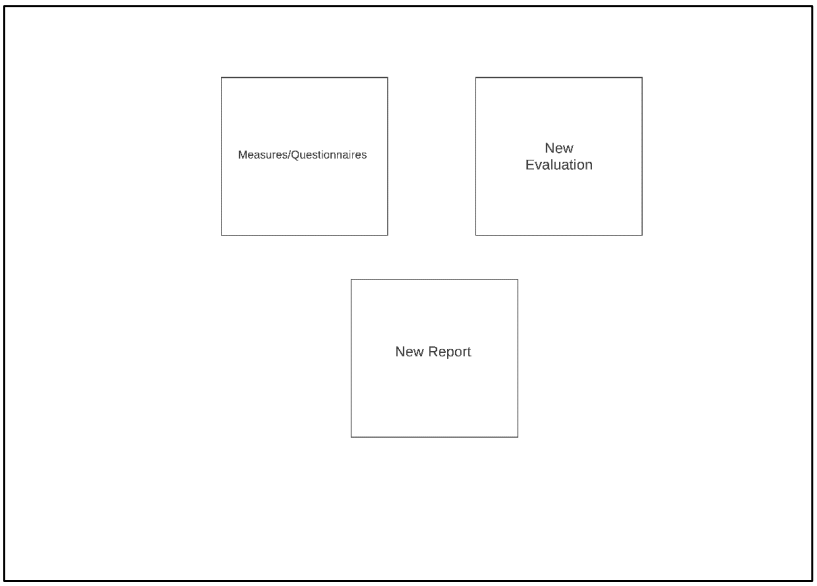
Dashboard



The intention of the ‘dashboard’ was to have simple options displayed to the user immediately as they logged in. Following discussions with Tenovus it was clear that they needed a clear and simple layout where there very clear intentional categories. This led onto the ‘actions’ page which very simply would request what action the user wanted to take. The later stage wireframes show how this was then combined into one dashboard.

Figure 14

Actions page



An important requirement for the interface was the ability to display and compare user-friendly graphs related to the data that had been collected.

Figure 15

Graphs and reports

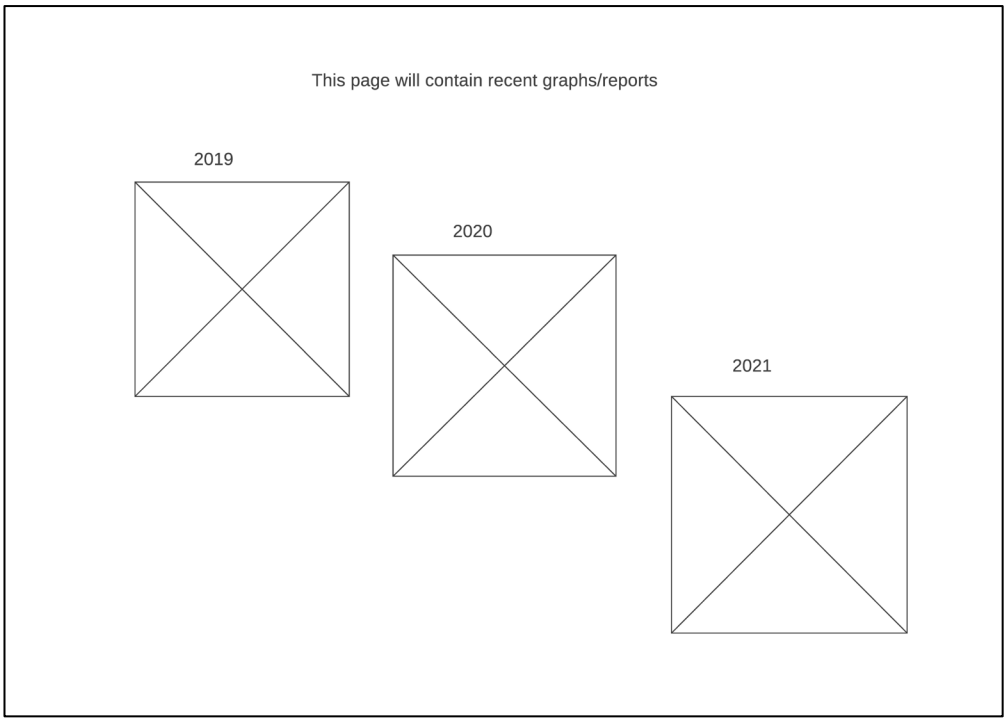
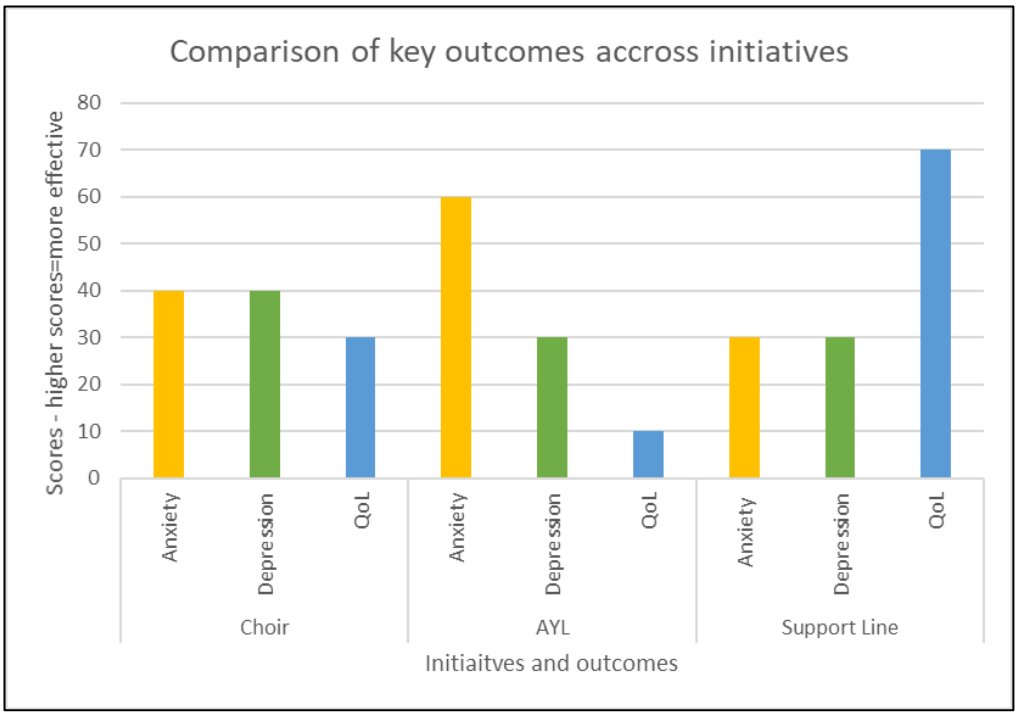


Figure 16

Exemplar comparison graphs for live data page



Stage two wireframes

These wireframes (Figure 17 and 18) were created by Vindico when they became involved with the PhD research. Initially the interface was to be developed alongside colleagues/supervisors from the School of Applied Computing, however following consultations with them it felt necessary to include an additional collaborator for this phase of the research. These wireframes allowed them to ensure they had fully understood the purpose of the interface and to showcase what was feasible within the timeframe and budget in regard to design, structure, layout and options.

Figure 17

Questionnaire exemplar page

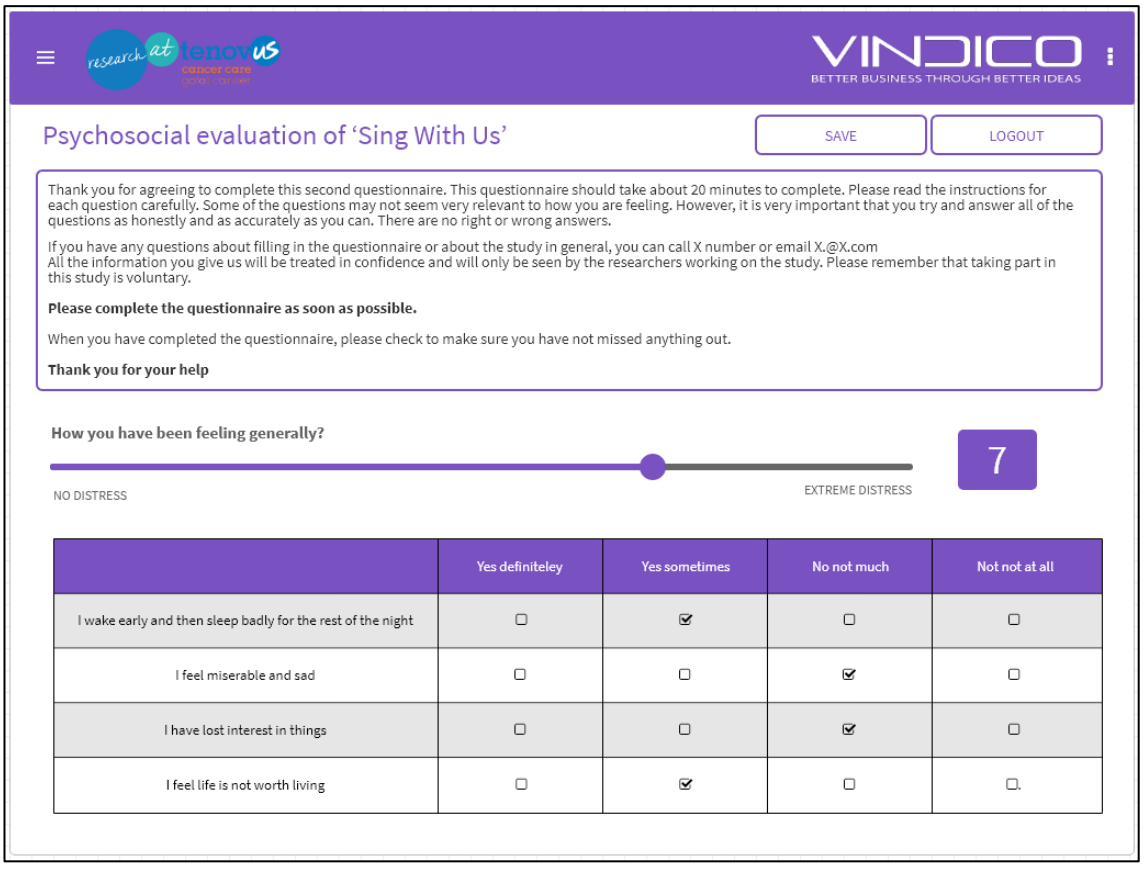
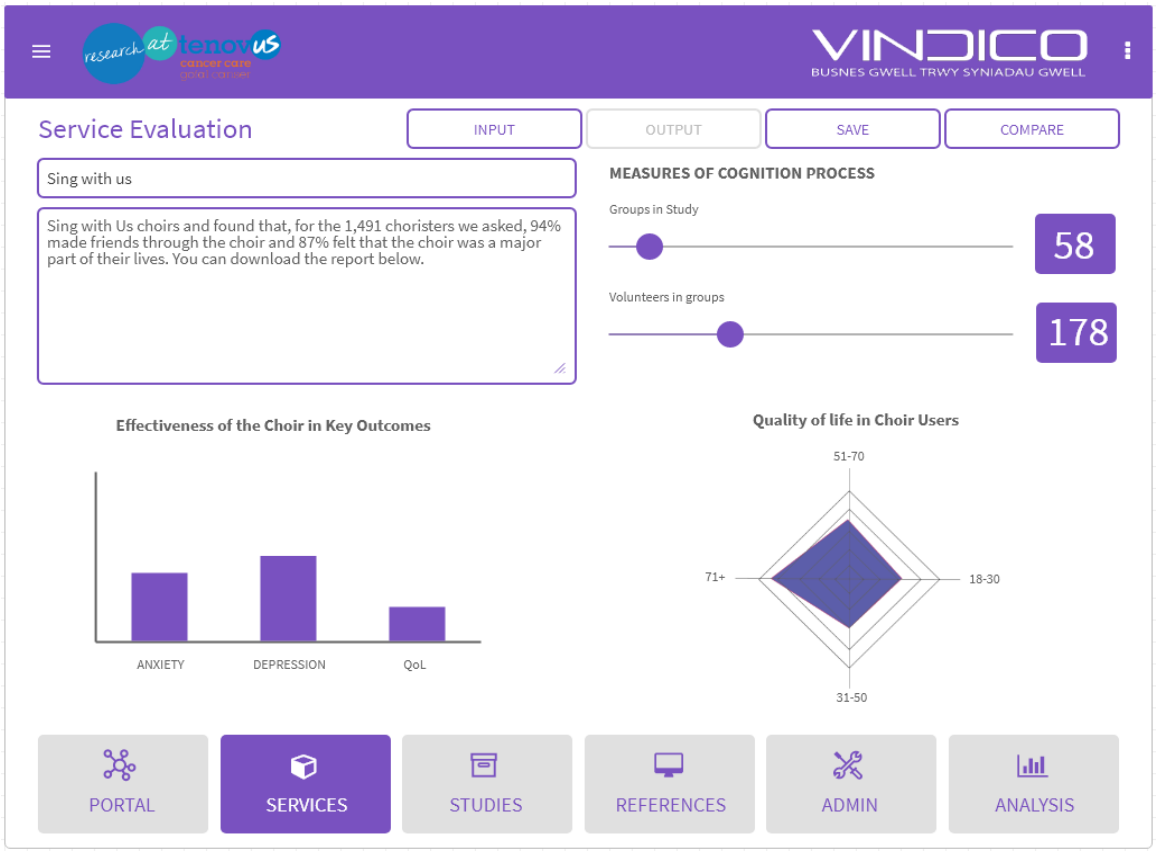


Figure 18

Exemplar results page



Stage three: Final prototype for evaluation

The following images show the final prototype of the T:POT interface. The entire interface was designed to co-ordinate with Tenovus Cancer Care's branding (orange, blue, white). Figure 16 shows the secure login page, which was kept simple, with options to register and reset the password. Figure 17. shows the final dashboard where each section is clearly labelled, however the efficacy of this was tested during the user experience evaluation discussed in more detail in the next section of this chapter.

Figure 19

Final login screen

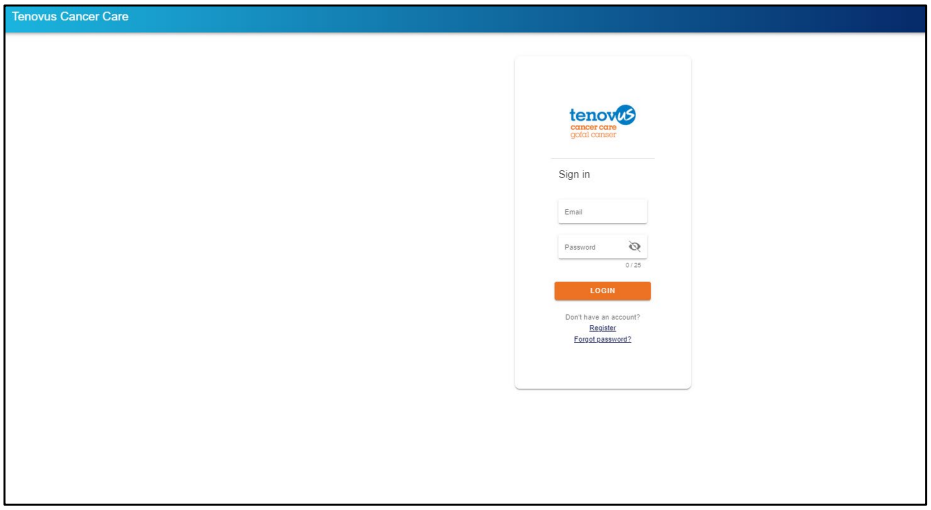


Figure 20

Final dashboard

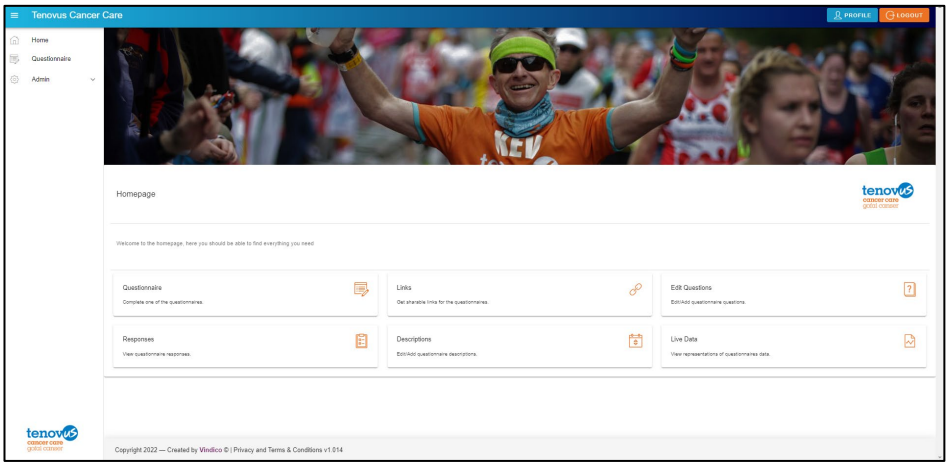
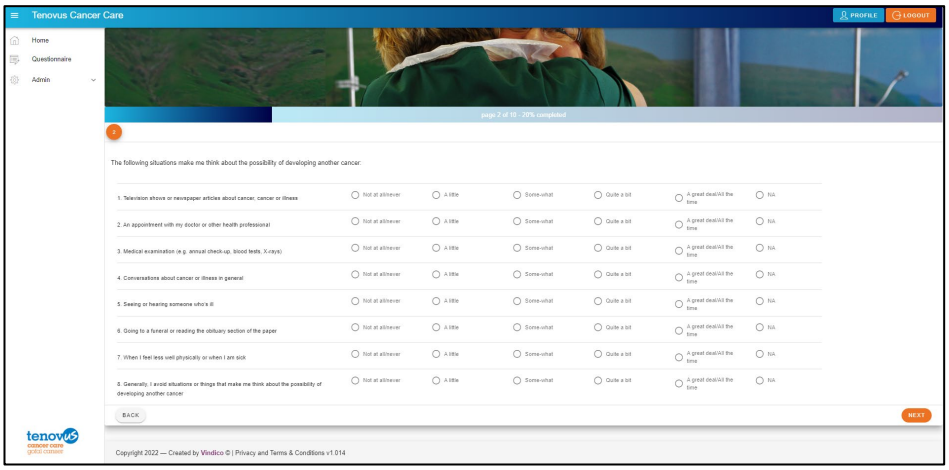


Figure 21

Final exemplar questionnaire page



User experience and usability evaluation of the T:POT interface

This section will discuss the process of conducting a user experience and usability evaluation on the data visualisation interface developed as part of this PhD research and a crucial element of the KESS funding. A detailed explanation of the interface development process and the background literature surrounding user experience evaluation has already been outlined in chapter three (methodology) and this chapter will explain how each stage of that development process was evaluated and how it subsequently progressed through to the final prototype. By the end of this chapter, it should be clear exactly what process was undertaken to ensure the data visualisation interface was fit for purpose. The following details the process undertaken to evaluate the usability of the T:POT interface. Due to the COVID-19 pandemic there were some issues with recruitment, meaning that part of this UX study had to be attached to another study and was the final step in a three-part study. The details of this are explained further in chapter seven. The following studies fall within the evaluation phase of this PhD and align with the testing and piloting stages of the MRC framework (Skivington et al. 2021).

User Experience Evaluation: Study One

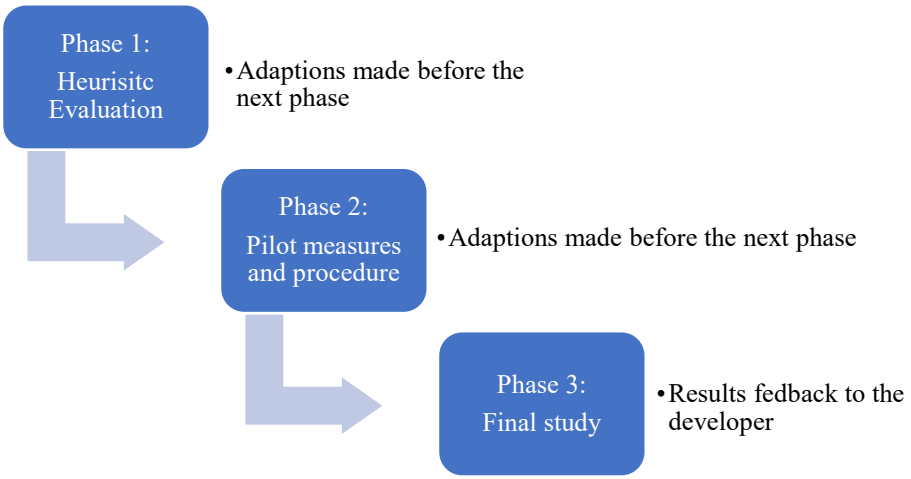
Aim

The aim of this study was to evaluate the user experience and usability of the data visualisation interface by completing a set of tasks relevant to the purpose of the final product.

Method

Figure 22

Phases of UX evaluation



Following the design and development of the T:POT interface, using a mixture of quantitative and qualitative evaluation methods, the usability evaluation was carried out in three phases as seen in Figure 22. Phase one consisted of a heuristic evaluation with two of the supervisory team who are experts in computing. Phase two piloted online user testing procedures and suitability of the proposed task list with two lay individuals and two colleagues from the Discipline of Psychology and Counselling. Phase three was the final study conducting user testing with four user groups consisting of academics, researchers, patients and Tenovus employees. All three phases were conducted online using Microsoft teams and Zoom, utilising the screen sharing, participant control and recording capabilities.

Full ethical approval for this study was granted by UTWSD ethics committee on 17/09/2018.

Participants

Participants for this study were different across each stage of the evaluation to fit the aim of each stage appropriately and so that the same participants were not evaluating the system again. Participants for phases one and two were recruited via opportunist sampling and phase three participants were recruited via Tenovus Cancer Care's staff email system. The estimated sample size for user experience evaluation studies is around five participants, this is enough to allow at least one participant to encounter a problem and is sufficient within the field (Nielsen, 2012).

Phase 1 – Heuristic evaluation: Two academics from the field of Applied Computing with expertise in user experience evaluation and database systems.

Phase 2 – Pilot: Two lay individuals and two academics from the field of Psychology and Counselling

Phase 3- Final study: Four user groups were identified for this phase

1. Academics/Researchers in any field
2. Patients/Service users with experience of cancer
3. Research and Evaluation/Heads of Service at Tenovus Cancer Care
4. Any other Tenovus Cancer Care staff (e.g., admin, fundraising, PR etc.)

Design

The study employed an online mixed methods usability design. Using participant observation, and follow-up quantitative questionnaires. For both the pilot and final study, participants were provided with access to the interface and asked to complete a list of tasks. Following the pilot study, some changes were made to the task list to increase the steps taken to get to the end goal. Table 35 shows the task goals and breakdown for the

final study. They were also asked to complete two follow-up questionnaires measuring usability and user experience of the interface.

Table 35

Task goals and breakdown for the final study

Order	Task goal	Task breakdown
1	To log into the interface using the details provided	Login using these details Username: Password: UWTSD2020
2	To find an individual response, identify their profile and scores, then return back to the home page.	Find participant responses Search for the response from a participant with the unique ID code of KAR0QUFRE2XRK Can you tell me which questionnaire they completed? Can you tell me which group they belong to? Can you open up their response to show their score for 'Quality of Life' Can you tell me if this score is good or bad? Close this view Return to the home page
3	Edit one question of a specified questionnaire	Find the edit questions page Search for question 5 of the HADS survey Edit this question (add or remove a full stop) Click save Close this view Return to home page

4	Explore the live data and interpret two graphs	Find and view the live data page Find the chart which shows anxiety and depression scores on different genders Select from the drop-down menu to only show MALE responses Can you tell me what you understand from looking at this chart? Can you find the chart which shows anxiety and depression scores on different age groups Select from the drop-down menu to show results from one specific age group Can you tell me what you understand from looking at this chart? Go back to the home page
5	Share the link to two specific questionnaires	Find the links to the questionnaires Choose to only send the HADS and FACT-G out to participants Click share Can you tell me what options you have to share the link to the study Go back to home page
6	Log out of the system	Log out

'Think Aloud'

The think aloud method is a cognitive engineering technique to help analyse the way in which people perform a behaviour or task, used most commonly when exploring interaction between a human and a computer prototype (Jaspers, Steen, Bos & Geenan, 2004). The think aloud method asks participants to verbalise their thought processes as they are completing a task, they can speak aloud any words or phrases that come into their heads whilst they are processing the actions to take to complete a task. For this study,

taking part in this process was not mandatory and participants were only asked to do this if they felt comfortable to do so. Using allowed a greater insight into the pathway that participants took to complete a task.

Counts

By using video conferencing software and enabling screen-sharing capabilities, it meant that observing a participant's behaviour on the screen was much easier. Looking for the accuracy of where participants clicked allowed some insight into whether they chose the correct option, whether they were able to complete the task, if they completed it using a different pathway, if the task caused any frustration, or a sense of giving up.

Time

By observing what the participant is doing and recording the video call, the time taken to complete each task was able to be observed. By looking at how long it takes to complete each task, how long spent on specific parts of a task and any particular elements which absorbed more time than others to gauge the ease of use. Acknowledging that technological confidence or internet speed, may play a role in the length of time spent on each task

Frequency errors

Observing frequency errors allow any misleading or misunderstood parts within the interface to be identified. These errors can lead participants to take the wrong pathway, slow them down or prevent them from completing a task. The same observations can be made for any visual elements of the interface, such as misinterpreting an icon or items appearing too similar.

Follow-up questionnaires:

User Experience Questionnaire (UEQ; Schrepp, Hinderks & Thomaschewski, 2014) – the UEQ measures six elements of usability and user experience using 26 pairs of contrasting attributes on a 7-point scale. For example, attractive to unattractive, inventive to conventional and creative to dull. These attributes capture the following factors of user experience.

- Attractiveness: Overall impression of the product (like/dislike)
- Perspicuity: Easy to learn/familiarise self with
- Efficiency: Can users solve their tasks without unnecessary effort/does it react fast
- Dependability: Does the user feel in control of the interaction? /Secure and predictable?
- Stimulation: is it exciting/motivating/fun to use
- Novelty: is the design creative/catch interest of other users

System Usability Scale (SUS; Brooke, 1986)

The SUS measures usability on a 10-item scale on a five-point Likert scale ranging from strongly agree to strongly disagree. It measures usability on a wide range of products such as hardware, software, mobile devices, websites and applications. Example statements include ‘I think that I would like to use this system frequently’; ‘I found the system unnecessarily complex’, and ‘I felt very confident using the system’.

Free text

Following the completion of both questionnaires, participants were given the opportunity to add in any other written feedback they had about their experience of completing the tasks using the interface.

Usability severity rating (Neilsen, 1994)

Using the Neilsen (1994) severity rating to categorise each usability issue identified through the user testing. Each usability issue is rated from 0 (not a usability issue) to 4 (usability catastrophe).

Materials

Due to the COVID-19 restrictions all user testing methods were conducted online and recorded via video conferencing software - Microsoft Teams and Zoom. Qualtrics online survey platform was utilised to disseminate follow-up questionnaires.

Procedure

For both the pilot and final study, participants were contacted and sent the study information sheet and consent to read prior to arranging a time and date for the user testing to take place. Once the online meeting was scheduled, participants were asked to re-confirm that they were happy for the call to be recorded and that they could stop at any time. Following the completion of the user testing, participants completed follow-up questionnaires and were thanked for their time.

Phase 1: Heuristic evaluation

A heuristic evaluation was conducted with Dr Kemi Ademoye, Dr Nik Whitehead and Dr Ceri Phelps. This consisted of a virtual meeting using Microsoft teams and the screen sharing capabilities. A walkthrough of the interface was conducted with various elements being tested and discussed. A number of visual and functional elements were identified that were suggested as changes for the next version of the interface. This information was collated into a document and formed a short summary that was then shared with Vindico. Following this, a virtual meeting was set up to go through the changes suggested and discuss the options available. Once the suggested changes were made (see table 36 and table 37 for a summary of the feedback and changes made) the next

phase of testing commenced. At this stage it was also made clear how to engage with users via video conferencing software as due to the COVID-19 pandemic the study needed to be made available online. Other recommendations at this stage included, sending the task list to participants via the chat function so they could only have access to one task at a time and not see what was coming next and, to set up the UEW and SUS follow-up questionnaires on Qualtrics so they could be sent to participants immediately after completing the tasks.

Table 36

Summary of heuristic evaluation process and feedback

Point raised	Suggestion	Action/researcher feedback
Response options could be sliders or radio buttons	Could do a/b testing for two different types of questionnaires so one would be all radio buttons and one all sliders	Is it worth doing a whole a/b testing for this? Could we just mix it up a bit and ask users what they think about them? Wondering whether this makes it too messy with Vindico – will ask Claudia her thoughts
Progress bar isn't effective (shows % of way through)	Could the progress marker instead show page X of X and %	Important to make sure the user knows how long it will take to complete at the start of the questionnaire. I like the page X of X, would this reflect the same on different devices/still be easy to read? – something to chat to Claudia about.
Unique ID number clarification and purpose	Do users actually need to know this information? They probably won't write it down so would their email address & date of birth suffice when using it to retract data AND track data across different time points	I think this is a good point. Need to clarify the purpose of the ID number with Claudia and maybe see how this looks in the interface that is behind the scenes.
Demographics not sufficient/need expanding	Date of birth instead of age, more gender options, display these in a drop-down menu, group options	All fine – these were just dummy data initially, so no proper thought given to actual demographics at the time just wanted to get some dummy data in there. DOB is probably better, but we do usually use age as a marker for things so it's working out how to do that if we only take DOB. Groups – I personally like how the group options are set up but as this increase it may need to be a drop down. (This currently needs another button for phase three – whatever that ends up looking like).

Point raised	Suggestion	Action/researcher feedback
Terms & conditions section not clear/could just skip over it	The 'hat' icon is placed closer to the wording of Ts&Cs to signify to the user that this is a drop-down menu. Alternatively set it up so that they have to click on it before they can check the box to say they agree.	Ts&cs will probably reflect confidentiality/GDPR stuff and will also need this function in the consent where they have to click on it to say they've read and agreed to it. (Also, if not agreed then they can't proceed).
How does it look on other devices	Using developer tools can view what the page will look like on various devices, this is important to make sure it works on all devices for users	Vindico have shown me this, this is something they check anyway but worth being shown how to check it
Visualisations – bit lacking, don't make much sense	Ask what visualisations are available to use and see which ones fit the data I am trying to represent	Agree with this, I think due to the dummy data it looks a bit weird –
Visualisations – only shows one service at a time	Potential for a drilldown method to explore the outcomes for services in more details – possible toggle options at the bottom. Makes more sense for ALL things to change depending on the toggle	This makes sense – really need them to sort the fact that we need to be able to compare outcomes across services – this will be easier to do when the proper toolkit is devised given that it will be based on the subscales.
Admin descriptors are too long/messy	Could just include the first 50 characters or so to indicate what that section is about – also the order needs to be a bit cleaner/more organised Vindico need to give me a WYSWYG editor to allow me to bold/change the display of wording	Agree it looks chaotic – It only makes sense to me because I've been looking at it for so long – this section is new, so Claudia hasn't had any feedback for this bit yet
Individual responses – traffic light system	Good visualisation with the traffic light system. Overall, it's clear where the problem areas for that person are. The Layout could be better, lots of white space. May be better to have all boxes the same size, turn into list formats (see teams for image)	Agree I don't think it's very clear/easy to read however Claudia just based that on the subscales I gave her so it's useful to know how that could look and to discuss other ways of displaying it
'Expand' icon	Currently uses an arrow bow – suggested that this changes to an 'eyeball' to better	I think this would be an interesting thing to look at during usability testing

Point raised	Suggestion	Action/researcher feedback
	explain that it contains more details	
Searching for people/responses	More ways to search, can we search per outcome/subscale as well as name/email/id etc The size of the 'pill's needs to change but the colours are good Data time point – fine but what happens when there's another data time point? If people use the same email address, is it just separate responses?	I think this is where Vindico thought the unique ID was useful but not likely that they will remember it so need another way of tracking people at different time points Suggested that this may be email & date of birth (people less likely to get this info wrong and definitely won't forget it).
Free text box answers – where are they displayed?	Couldn't find these but I don't think anything has been typed in really so worth testing this out properly to see if they appear anywhere Suggested that a word cloud may be a good way of displaying these on the live data page	I like the word cloud idea – will see if this is something that can be done (links back to earlier comment about asking what data visualisations are available to use)

Phase 2: Piloting procedures

Following the changes made to the interface following the heuristic evaluation, the procedures for the final study were piloted with four participants. The aim of this step of the user testing was to test the procedure of recruiting and conducting an online user test, using the recording and screen share capabilities of each platform. In addition to this the pilot also tested the task list which had been developed for users to work through as part of the user test. This step required a maximum of three people to test out these procedures, however four were recruited to have a balance of academics and lay individuals. Two of these were academics from the psychology department and two were lay individuals who were recruited via email. This process allowed the function of both Microsoft Teams and Zoom's screen sharing, participant control, and recording

capabilities to be tested and also the participant task list. Following completion of the task list, participants were asked to complete the two follow-up questionnaires before ending the video call. During the procedure pilot it was identified that asking participants to 'Think Aloud' whilst trying to complete the tasks would be beneficial and also during the follow up questionnaire but to make clear that this was not a requirement.

Phase 3: final study

For the final study a list consisting of 30 individual tasks was finalised to be completed by the participant. There were six main tasks which were broken down into individual steps in order to best test the pathway that participants took to try and complete the task. Participants were recruited via email and were sent a link to the online study information sheet and consent form. Participants were required to complete the consent form prior to taking part as the video call needed to be recorded for the purposes of analysis. Once the participant was happy to take part a suitable time and day was arranged, and the appropriate video conferencing software chosen. Participants joined the video call, and the process was explained before starting. They were asked to 'think aloud' during the process if they felt comfortable so as to add more value to the thinking process behind the path they took. The screen was shared with the participant, and they were able to take control of the screen and had the ability to type and click as if it were their own. This allowed full control in case of anything going wrong with the interface. Each set of tasks were copy and pasted into the chat function of either Microsoft Teams or Zoom one at a time so as not to overwhelm the participant. Checks were done throughout that the participant was OK and happy to continue. If a participant was becoming frustrated or repeatedly not completing the task, it was advised that they move on to the next one. At the end of tasks, they were shown the preferred pathways for each task which boasted speed and efficiency. It was

explained before and throughout that it was not a test of their ability to complete the task but a test for how user friendly the interface was. Following completion of the tasks participants were asked to complete two online follow-up surveys: User Experience Questionnaire (UEQ; Schrepp, 2014), System Usability Scale (SUS; Brooke, 1986), and also presented with a free text box for any additional feedback. They were given the option to complete these whilst still on the video call or in their own time, each participant opted to complete these whilst still on the call and were happy to discuss their choice of answer for each question.

Results

Three stages of user testing were conducted in this phase of the research. A total of 12 participants took part in this phase and were a mix of academics, Tenovus staff and lay individuals. Demographic information was not collected as it was not relevant to the study aims, however job role/eligibility to take part was collected. This phase of the research was conducted primarily online via Microsoft Teams and Zoom due to the covid-19 pandemic restrictions throughout 2020 to 2021.

Heuristic Evaluation

A heuristic evaluation was conducted with two Applied Computing experts. This process took place via video call and lasted around 90 minutes. The heuristic evaluation identified a number of visual and functional elements that needed to be addressed prior to final user testing. A summary of these findings can be found in Table 37.

Table 37

Visual and functional elements

Item	Comment/Feedback	Change made?
Progress bar	Show page X of X as well or in place of percentage bar	Yes
'Terms & conditions'	Move icon closer to text to make it clear this section is expandable	No
Live data	What other data visualisations are available to show the live data?	Other visualisations used
Admin descriptors	Shorten the description of each section	Yes
Editable pages	Where there is an ability to edit text – could there be a tool put in to change text to bold/italics/size etc.	Yes
Individual responses (traffic light system)	Traffic light system is great – could the layout of the data/text change to reduce white space/make clearer.	Yes
Searching for people/how they are grouped	Where it says which group, they are part of – the colours are good – could all of the boxes be the same size?	Yes

Functional elements

Item	Comment/feedback	Change made?
Unique ID number	Can the persons email address and/or date of birth be used as a tracker	Yes
Demographics	Age-> Age and/or date of birth Gender -> Male, Female, Other, Prefer not to say	Yes Yes
Live data	Ability to compare services against each other on the same page/same graphics	Yes – same graphics
Searching for people	Can you also search for scores? E.g., if someone scored above 10 on a particular scale – creating an ability to highlight an 'at risk' group (above 10 is just an example)	No
Data time point	How would displaying multiple entries for people work? E.g., follow-up data	Not addressed yet
Free text box	Where does this data show up?	Yes

Could it be displayed on the
'live data' page and what types
of visualisations are available?
E.g., a word cloud

Pilot phase

Four individuals took part in the first step of the user experience testing, they were two academics from UWSTD Psychology team and two lay individuals. This allowed the study procedures to be tested and refined in preparation for the final step of user testing. The pilot phase allowed both Microsoft Teams and Zoom to be trialled, both programs offer session recording, screen sharing and participant control functions. Overall neither of these programs outperformed the other, both seemed to be reliable and user-friendly enough for participants to engage with and the recordings were easy to access and of good quality. With regards to the procedures, it was evident that the tasks would work better if they were broken down further. Some of the tasks were more difficult than others and the placement of these caused some frustration amongst the four participants, therefore it was decided that the task list should start with easier and more manageable tasks with more difficult tasks in the middle and then closing with an easier task. Some of the common observations that came out of this phase of testing include:

- Users are unsure about the use of the search function when asked to find and edit a question. Most participants used the search function but did not use it to its full capacity to make the task easier. This function saves time and effort but is not obvious to users so far.

- Users are able to interpret the traffic light system well, without needing to know more about the individual they can see a snapshot of their data and interpret these quickly which is useful and efficient.
- Users found the live data page to be clear enough to navigate, however some of the values could be clearer, possible addition of a key for the charts. It was noted that when toggling between genders/age groups the numbers on the axis change and this could be something that needs to be pointed out to users, so they do not make inaccurate judgements
- Small observation that users 'log out' of the system using a path that takes longer and they do not use the icon specifically for logging out. This icon may not be clear enough (Semi-circle with an arrow exiting). This could perhaps change to 'log out'.
- When piloting with users with no knowledge of Tenovus they were unsure of the acronyms used for the services so a pop-up function which defines these terms and/or a page for a glossary of terms may be useful
- When searching for a specific question, the questions do not appear in order which proves frustrating for the user. Although you can 'sort' them to appear in order you cannot sort them per questionnaire.
- Most users have had difficulty seeing the scroll bar on the right-hand side of the page. It is currently grey so this may need to become more obvious, however this could also be because the screen is being shared and it may not be totally visible to the user.
- One task asks the user to find and share a questionnaire, each user has taken the wrong path when first attempting this task. The correct path is the button with 'links but users are choosing the one which says 'questionnaire' which is set up to allow you to go through the questionnaire and enter data into the system (useful function for being able to input hard copy questionnaires should this be required).

- Overall users are finding the system intuitive, easy to navigate and enjoyable to use.

There were no changes made to the interface at the end of the pilot study. The only changes made following the pilot study were to make the task list clearer by breaking it down into smaller steps and to encourage participants to think aloud.

Final study results

The final study included six participants across two user groups. Three participants were employees within Tenovus Cancer Care and were all heads of services and research. The other three participants were all academics from the Psychology and Counselling team within UWTSD. User tests took between 30 and 60 minutes to complete and all participants completed the follow up questionnaires whilst still connected to the video call. All user tests in this phase were conducted using Microsoft Teams as they all had access to it and felt confident using it. Table 38 depicts overall observations for each task.

Task 1

Task one required participants to log into the system using the details provided. There were no issues with this task and participants navigated the system quickly.

Task 2

Task two required participants to search for a particular response and to find out information about their profile and overall scores. Participants generally found the correct response however many took a longer path to complete this task. Around 1/3 of the participants utilised the search function in this section which is designed to make this process quicker and more time efficient. It was clear that this option is not made clear enough to participants and that making this more prominent would be useful. After the response was located, participants were required to expand the profile of the respondent,

this generated a lot of clicks on different points of the interface until the correct icon was located. This task did not take up a lot of time once the participant response was located.

Task 3

Task three required participants to find and edit a particular question within one of the questionnaires on the system. Participants found this section very quickly when navigating from the home page. This task saw similar problems as task two where the search function was not utilised by every participant which made the path to complete the task longer and more cumbersome to locate. Following the location of the correct question all participants managed to edit the question and save the changes. Some participants noted that it would be useful to have 'pop up' when hovering over an action button to describe what action that button represented.

Task 4

Task four was the longest of all six tasks and required participants to explore the 'Live Data' page on the interface. This task tested both the capacity to search for the correct charts and toggle between demographics to enable the data being displayed to change and required interpretation of the data. It was made clear at the start of the study that this was not a test, the task was specifically worded to encourage participants to just describe what they felt the chart was telling them. Overall, all participants managed to find the correct charts and toggle between gender and age to show different results. It was highlighted that some of the charts needed better labelling on their axis points and the use of a key or legend would be beneficial. Participants commented on how interesting this part of the interface was and were genuinely interested in the data. This suggests that the charts are engaging and easy to read, with some minor changes needed to enable the interpretation of data to become clearer. Changes such as: bigger text size on axis labels, pop-up information to explain the axis changes when toggling between demographics, and a clearer key alongside the charts. The traffic light system used within the interface was

recognised from task two therefore some participants were able to determine the results on the charts based on the colour before looking further into the actual data being presented.

Task 5

Task five required participants to go through the process of finding a survey link which combined two surveys and explore the options that were available to disseminate the questionnaire to service users. Overall, this was the most problematic task, almost all users took the wrong path to complete this task. The 'Questionnaire' and 'Links' options are located side by side on the home page and participants opted for 'Questionnaire'. This function on the interface currently allows you to complete a questionnaire as an admin user which is a function that was created to input hard copy questionnaire data if required. Participants were generally frustrated during the process of completing this task and were eventually directed back to the home page and advised to try a different path. Once participants were directed back, they then took the correct pathway to complete the task. Generally, participants were able to recognise that survey combinations were available to be disseminated, however some participants chose to share the questionnaires separately. In order to overcome this issue, the distinction between these two functions on the home page should be made clearer by changing the wording to better reflect their function.

Task 6

The final task required participants to navigate back to the home page and log out of the system. Participants were able to complete this task quickly but did not choose the direct path to log out. This is where the 'pop up' for each button would be useful as users would be aware of the action that would be taken if they clicked a particular button.

Table 38

Observations following pilot and final study

Notes: E= essential to fix, PNE= preferred but not essential to fix

Task	Observations and Usability Issues	Actions needed	Essential?
1. To log into the interface using the details provided	• Very clear and simple	No usability issues identified	
2. To find an individual response, identify their profile and scores, then return back to the home page.	• Automatic search bar function not utilised by 50% users • Almost all users were able to open up participant responses and interpret the data using the traffic light system • Functions that make this process quick and easy such as search bar and sorting, were not utilised effectively as they were not immediately obvious. • Overall, generally impressed with the search and sort function when shown at the end of the testing • Users liked seeing the drilldown of data and found it easy to interpret because of the traffic light system. • Users able to clearly identify the profile of the respondent and interpret it clearly (which group they belong, what questionnaire they completed)	• Make the icons/labels for searching and sorting more prominent. • Pop up function when hovering over icons could help direct users to the quickest route	E PNE
3. Edit one question of a specified questionnaire	• 90% of users did not utilise the search function for finding a specific question to edit. This task took longer to navigate as there are a lot of questions to go through. • Users did not generally use the sorting buttons but those that did, thought this function was very useful • Users generally spent a lot of timing looking for the correct question to edit, without realising the functions in place to make it a quick process.	• Make the icons/labels for searching and sorting more prominent. • Pop up function when hovering over icons could help direct users to the quickest route • Important element to be included in the user guide	E PNE

Task	Observations and Usability Issues	Actions needed	Essential?
	• Users commented that once this process was explained it would be quicker to navigate next time • Users became more frustrated with this task due to manually searching	that will be written for Tenovus.	E
4. Explore the live data and interpret two graphs	• All users navigated to this page with no issues • All users commented on the smaller size of the graphs with no ability to zoom/enhance • Axis titles and key/what the graph was telling users was not overly clear • Users liked the live element of the graphs, and they could interpret the data on a basic level • Users able to toggle between groups to show different demographics • Users commented that being able to see toggled options side by side would be useful • One user commented that the axis changes when toggling between groups but there is no warning so on the surface could misinterpret the data based on visuals. • Most users identified that the traffic light system was consistent throughout but found the key at the top useful to refer back to if needed • Users were generally interested and engaged by the data being displayed	• Better labelling of charts – axis and keys needed (this would be a useful function for admin to be able to edit or add) • Ability to compare two groups next to each other rather than toggle between the two • Generally better labelling and explanation of what each graph is measuring	E PNE E
5. Share the link to two specific questionnaires	• This task had the most errors and took the longest time to get to the correct outcome. 90% needed intervention to guide them to the correct outcome • Users clicked on ‘questionnaire’ which allows you to view/enter data rather than disseminate • 90% users did not realise you could combine which questionnaires to send out and attempted them separately	• Button labels need to be clearer to show that ‘Questionnaire’ is to view or add data and ‘Links’ is to disseminate the questionnaires. Slight name change needed • Some blurb needed on the ‘Links’ page to briefly	E E

Task	Observations and Usability Issues	Actions needed	Essential?
	• Once destination was reached, users were able to correctly identify the function to 'share' and to which platforms they had as options • Users commented that the symbol that looks like a 'link' next to 'questionnaires' is what confused them • Users became frustrated with this task due to not getting the right outcome initially	explain that questionnaires could be combined without the need to send separately	
6. Log out of the system	• Almost all users clicked on the icon that represents 'user profile' to log out of the system instead of the button which allows them to log out directly • Generally, did not take long to log out however some users commented that a pop-up over the icon which says log out could be useful OR changing the icon to simply say log out	• Consider changing icon/button which represents log out	PNE

User Experience Questionnaire

The UEQ produces six subscale scores. Subscales include Attractiveness, Perspicuity, Efficiency, Dependability, Stimulation and Novelty. There is no overall scale score for this measure as the value cannot be interpreted accurately. Table 39 shows the mean scores and standard deviations for each subscale. Overall subscale scores are calculated on a scale from -2 to +2 with higher scores equalling better outcomes (Figure 20). Each element of the interface scores well across each subscale, Attractiveness and Stimulation have the highest ratings overall with Dependability having the lowest rating. Despite Dependability being rated the lowest, it is still considered to be a good score overall. Individual items within each subscale were almost all positively rated with the exception of annoying to enjoyable (M=0.8), boring to exciting (M=0.6), unpredictable to predictable (M=0.1), obstructive to supportive (M=0.0), usual to leading edge (M=0.4) and conservative to innovative (M=0.8) which all received neutral ratings. There are benchmark standards to compare your results against which are provided by the authors of the UEQ. This comparison can be seen in Figure 24 where the interface scores range from below average, to good.

Table 39

UEQ mean subscale scores and standard deviations

Scale	Mean	*SD*	N
Attractiveness	1.648	0.788	9
Perspicuity	1.500	0.927	9
Efficiency	1.333	1.237	9
Dependability	1.028	0.861	9
Stimulation	1.667	0.673	9
Novelty	1.361	0.876	9

Figure 23

UEQ Subscale mean scores from -2 to +2

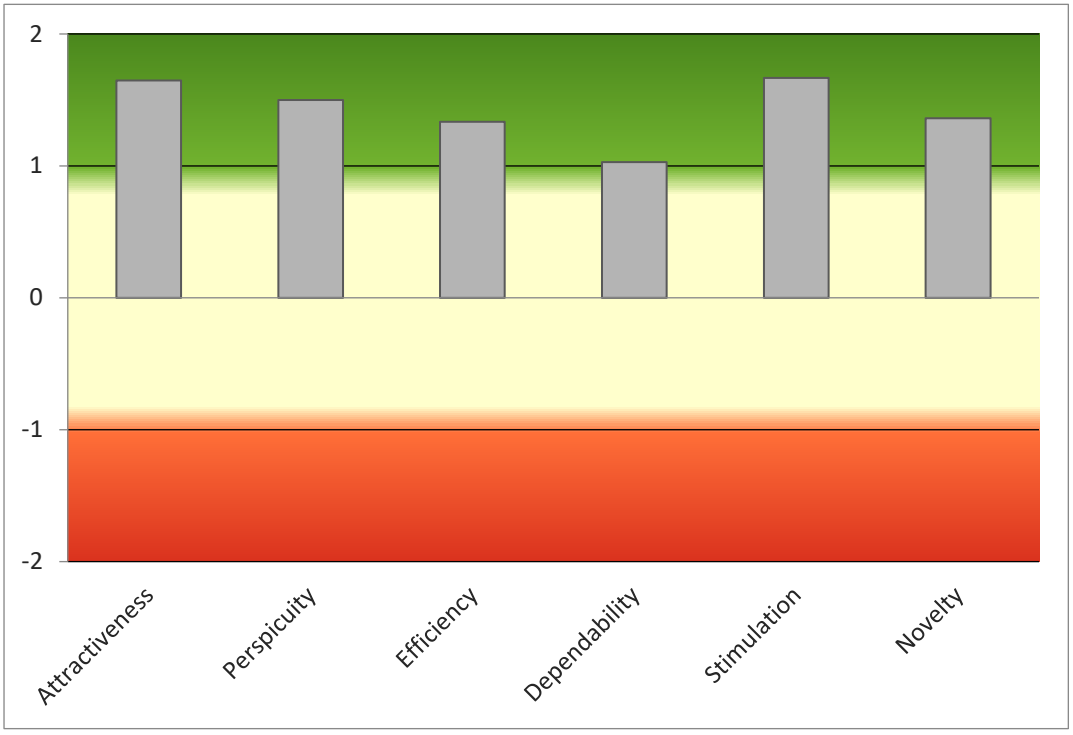
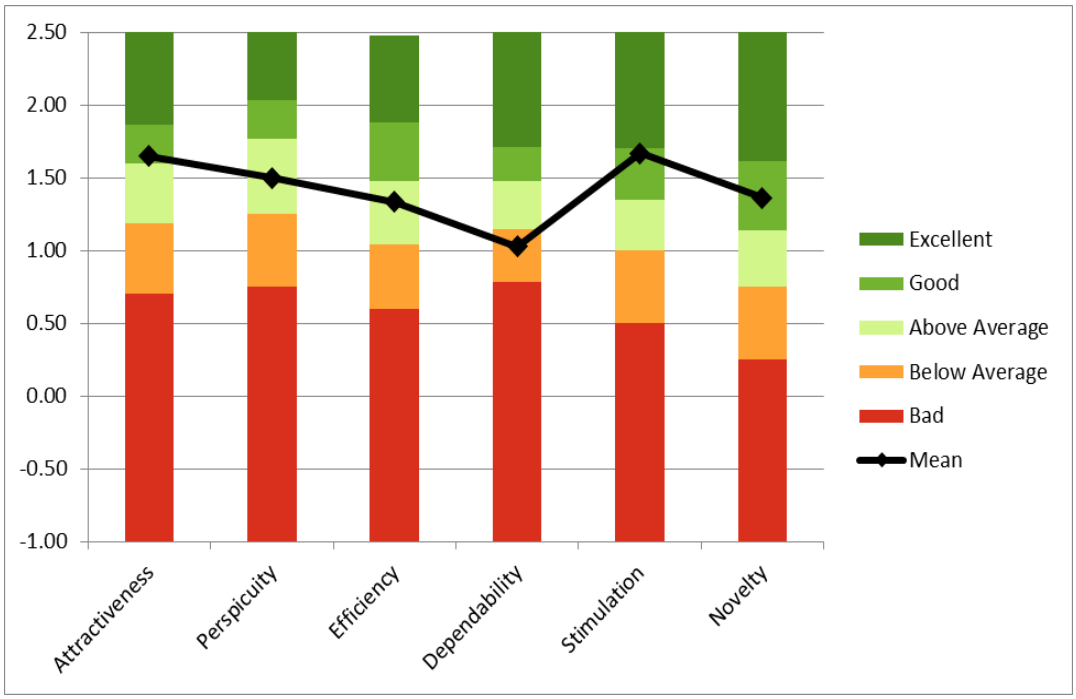


Figure 24

Results of the UEQ in relation to the benchmark standards

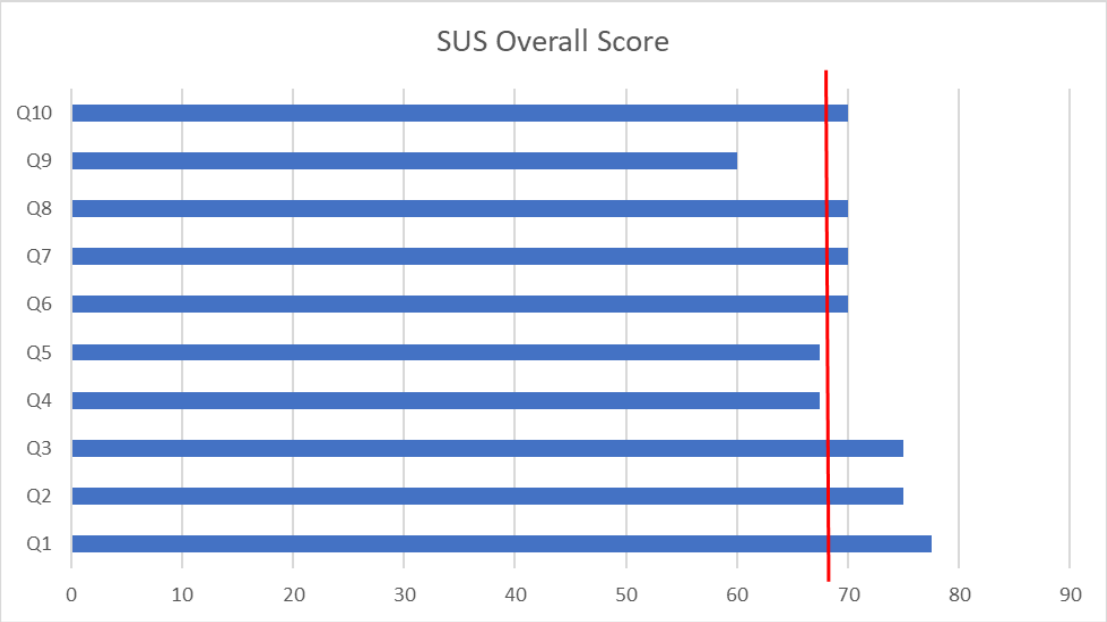


System Usability Scale

The System Usability Scale consists of 10-items measuring the usability of a system. Items are scored from strongly disagree to strongly agree with a numerical value from one to five. Overall scoring for the SUS requires items to be adjusted prior to calculating a total score. Odd item scores are subtracted by one and even item scores are subtracted from five. Once these scores are normalised by multiplying the total by 2.5, each score is compared against the benchmark average of 68. Scores that are 68 and above are considered to be above average, and scores below 68 are below average. Seven out of ten items scored above average, items measuring frequency, complexity and ease of use scored the highest, items measuring technical support, integration and confidence scored below average with confidence scoring the lowest overall.

Figure 25

A graph showing overall scores for each item of the SUS and the benchmark



Free text

The system looks great and is easy to navigate through the various different parts. It is not too complex and has been set out nicely and 'makes sense' when going through the tasks set out by the researcher and when considering what a service user would be looking for when using the system themselves. The graphs that display the information on depression and anxiety are a little confusing and quite small - it is easy to see where the two separate graphs are for gender and age but only after you have looked at it more than once. The graph for gender (circles with specific numbers) are much easier to read than the bar charts (as displaying the information for D and A across age groups), also. I think that it would be easy for anyone to be able to navigate this system once being introduced to the various parts and I think that taking part in this pilot would allow confidence to develop before using the system individually.
With no prior knowledge of using the system, I was able to easily and intuitively navigate it.

I liked the colourful info graphics, and the layout of the pages were easy to navigate. A help option may be useful to have if a person was unsure about what to do next.
Once I had a sense of the parameters, I found the system user friendly and intuitive. Would be very helpful to have someone to support the process at first.
Very clever and easy to use. The live data function was innovative and clear to read.

Overall severity of issues

Severity rating	Issues
0 Not a usability issue	• Log out button was often missed on the first attempt but did not cause any significant problem or delay
1 Cosmetic problem, fix if extra time available	• Ability to compare groups next to each other instead of toggling between them
2 Minor usability problem, fixing is low priority	• Not obvious you could search the participants or sort people by group, or measures etc. • suggested that a pop-up whilst hovering over icons could help • Ability to make the charts on the live data page bigger or zoom in
3 Major usability problem, fixing is high priority	• Search function for editing questions not totally obvious, caused delays and errors • Chart labels need to be clearer, including axis changes and a key explaining each chart • Button labels on the home page need to change to better differentiate between viewing the questionnaire to add data and disseminating the questionnaire – caused errors 90% of the time • Blurb needed on the 'links page' to explain what that page is for, icons not totally obvious for everyone
4 Usability catastrophe, imperative this is fixed before release	• No catastrophic issues identified

Conclusion

The results of this study suggest that the T:POT interface was perceived positively and was generally easy to use and people reported being happy to use and would like to use it more in future. The user experience questionnaire highlighted that all of the subscales scored highly against the benchmark standards, particularly attractiveness, stimulation and perspicuity, suggestion that the entire interface was clear, attractive and stimulating to engage with. One area where the interface scored lower was dependability. A possible explanation for this subscale scoring lower may be a result of this being conducted via video call using screenshare. There were multiple time points where there was a lag in an action taken or the system froze, however this was less about the interface and more about the strength of connection on both sides. This user experience evaluation was originally due to be conducted in person at Tenovus Head Office, however, following the covid-19 pandemic restrictions, adaptions were made to the data collection to facilitate it online. Future evaluations that are conducted online may look towards software that is designed for this function or, removing the screenshare function which would allow but also rely on the user to be able to load everything on their end.

The results of this phase of the study were collated and presented to Vindico in March 2021 where their team decided that all of the issues identified could be addressed in the timeframe and budget available for the PhD research. The following months were spent working with the junior developer on the team, so each issue was addressed, and tweaks were made to the interface. Once the interface was finalised it was able to progress to the next phase of user testing that included the patient facing front which is discussed in the next section of this chapter, and to be used in a live psychosocial evaluation of a Tenovus service, the results of which are discussed in the following chapter.

User experience evaluation: Study two

Aim

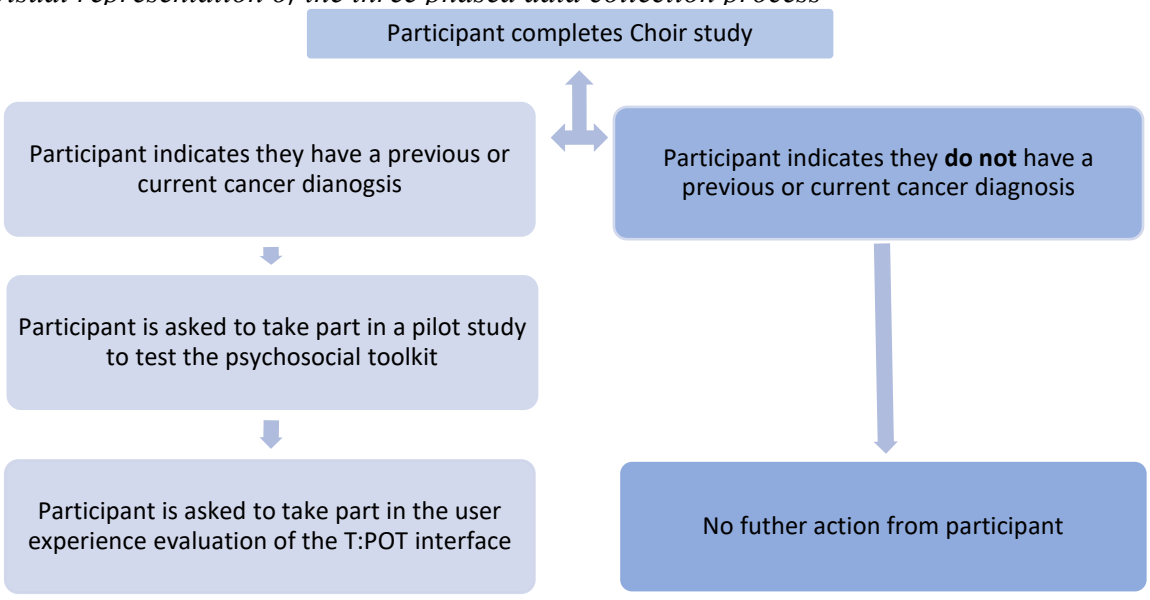
To assess the usability and user experience of the service user facing front of the T:POT interface.

Method

This study was conducted as part of a three-phase data collection process. Data collection was primarily quantitative with the only qualitative data being collected via free text at the end of the surveys. This study employed the User Experience Questionnaire (UEQ; Schrepp, Hinderks & Thomaschewski, 2014) and the System Usability Scale (SUS; Brooke, 1986) to assess the user experience and usability of T:POT with people with a cancer diagnosis.

Figure 26

A visual representation of the three phased data collection process



Participants

This study aimed to recruit individuals aged 18 or above who had a current or previous cancer diagnosis and had used services provided by Tenovus Cancer Care. Participants were recruited via Tenovus following phase one of the data collection process which asked those who had indicated they had a current or previous cancer diagnosis if they would be willing to take part in further research. A total of three participants completed this study and demographics were not collected as it was just relevant that they had a current or previous cancer diagnosis and as they had already completed two previous questionnaires it reduced response burden.

Design

This study was part of a three-phased data collection process whereby two quantitative measures were used to assess usability and user experience and a final qualitative free text box. Participants all completed the same measures and were not split by groups.

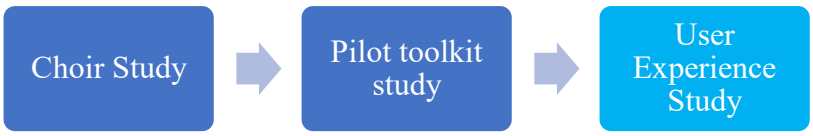
Materials

The three phases of data collection were all conducted online. This user experience study used Qualtrics online survey platform to deliver the questionnaires to participants via a URL link which was embedded into the T:POT platform. The User Experience Questionnaire (UEQ) and System Usability Scale (SUS) were used for this study, they are discussed in more detail earlier in this chapter as the same measures were used for both user experience evaluation studies. There was an additional free text box at the end of the online survey to collect any further qualitative data from participants.

Procedure

Figure 27

Participant pathway to completing UX study



Participants were recruited via Tenovus Cancer Care via their choir leaders. Choir leaders disseminated the study link to phase one of the data collection process (return to choir questionnaire). Participants were asked to indicate consent at the start of each phase to ensure they were fully informed about taking part and had the opportunity to stop or withdraw. Participants were all individuals who had attended a 'Sing with Us' choir and were asked to indicate whether they had a current or previous cancer diagnosis. Participants who indicated they had a cancer diagnosis were directed through the choir study and presented with a different final page than those who did not. The final page of the survey invited participants to take part in the next phase of data collection. Participants were asked to click on the hyperlink which took them to the T:POT interface where they completed the psychosocial toolkit pilot study that was developed as part of this PhD research (see chapter 7). At the end of this phase of data collection, participants were presented with another information sheet and hyperlink inviting them to take part in the final phase of data collection. This hyperlink took participants back to Qualtrics where they were asked to complete the UEQ and SUS questionnaires and a subsequent free text box for any additional qualitative information. Participants were thanked for their participation and reminded throughout that it was entirely voluntary and confidential, and that they could stop at any point (See Appendix E for study materials).

Results

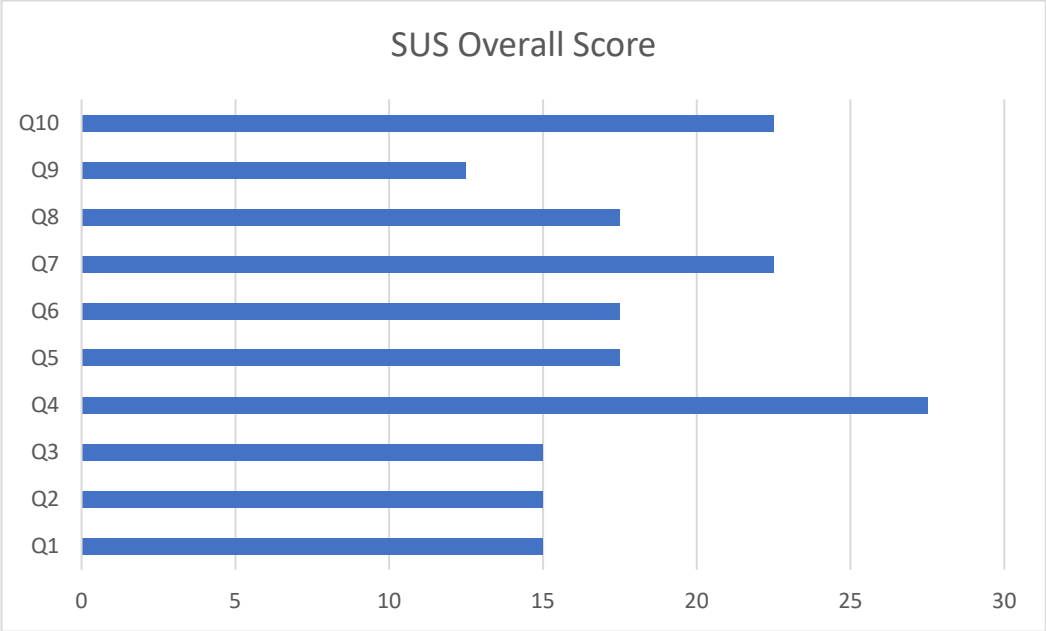
A total of three participants completed the user experience questionnaires. No demographic data was collected however all participants indicated they had a current or previous cancer diagnosis and were all current or past members of Tenovus Cancer Care's 'Sing With Us' choirs.

System Usability Scale (SUS)

The System Usability Scale consists of 10-items measuring the usability of a system. Items are scored from strongly disagree to strongly agree with a numerical value from one to five. Overall scoring for the SUS requires items to be adjusted prior to calculating a total score. Odd item scores are subtracted by one and even item scores are subtracted from five. Once these scores are normalised by multiplying the total by 2.5, each score is compared against the benchmark average of 68. Scores that are 68 and above are considered to be above average, and scores below 68 are below average. The results of this study show that all items scored below the benchmark standard, however this is only based on the data from three participants and therefore may not have been enough to work out an average score. Although none of the items met the benchmark standard, items measuring the need for assistance and the speed and ability to learn the system all scored highly indicating that the interface was simple to use and did not need any prior knowledge before using it. Despite these scores the item measuring how confident a user was in using the interface was rated the lowest, closely followed by items relating to frequency, complexity and ease of use were all rated low.

Figure 28

Overall SUS scores



User Experience Questionnaire (UEQ)

The UEQ produces six subscale scores. Subscales include Attractiveness, Perspicuity, Efficiency, Dependability, Stimulation and Novelty. There is no overall scale score for this measure as the value cannot be interpreted accurately. Table 40 shows the mean scores and standard deviations for each subscale. Overall subscale scores are calculated on a scale from -2 to +2 with higher scores equalling better outcomes (Figure 29). Each element of the interface scores fairly average across each subscale, Attractiveness and Dependability have the highest ratings overall with Novelty having the lowest rating. Overall, each subscale was positively rated (Figure 29) and individual items within each subscale were almost all positively rated with the exception of boring to exciting (M=-0.3), slow to fast (M=-0.7), complicated to easy received a very negative rating (M=-1.0) and unlikable to pleasing (M=-0.3). There are benchmark standards to compare the results against which are provided by the authors of the UEQ. This

comparison can be seen in Figure 30 where the interface subscale scores are almost all rated below average against the benchmark standards, except for dependability.

Table 40

UEQ subscale means and standard deviation

Scale	Mean	*SD*	N
Attractiveness	1.056	0.948	3
Perspicuity	0.917	0.520	3
Efficiency	0.833	0.629	3
Dependability	1.333	0.946	3
Stimulation	0.833	1.422	3
Novelty	0.250	1.000	3

Figure 29

UEQ Subscale mean scores from -2 to +2

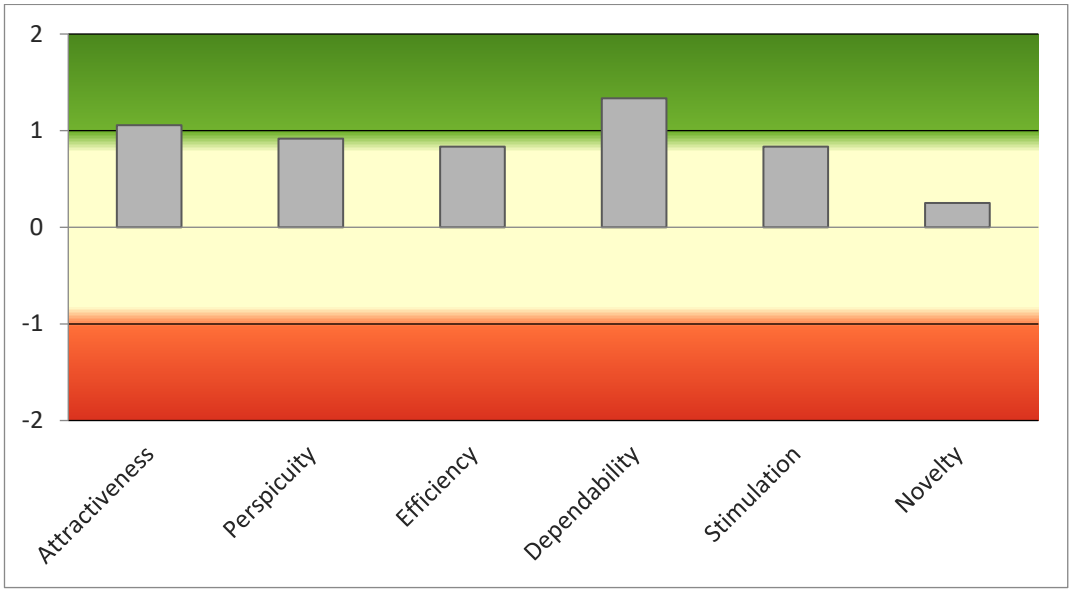
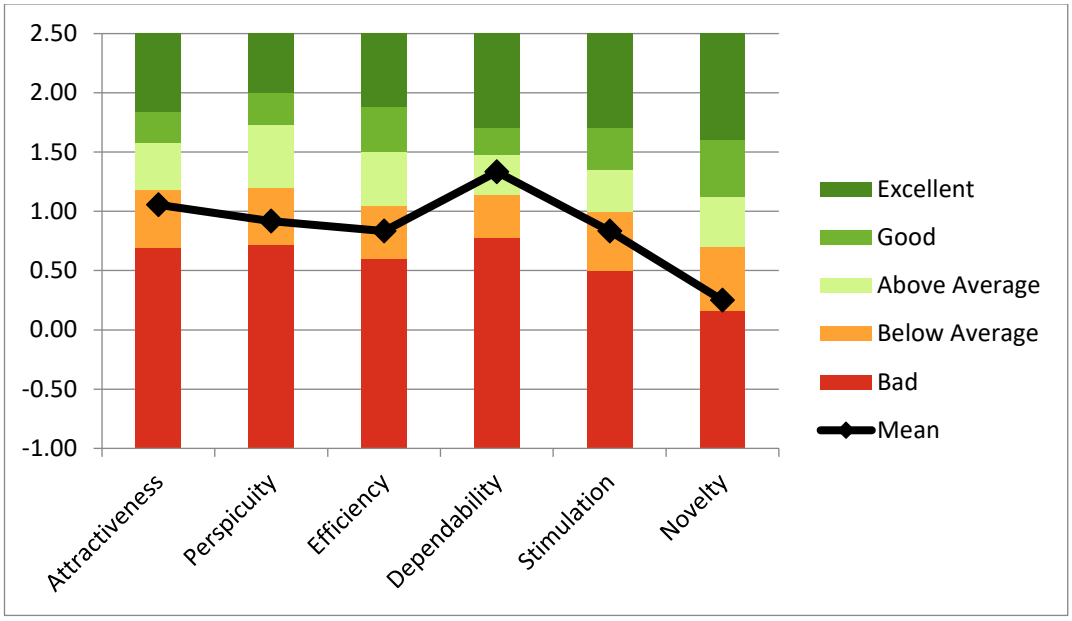


Figure 30

UEQ Subscale mean scores compared to the benchmark



Discussion

The results from this study reflect the user experience evaluation of the patient facing front of the T:POT interface. Overall, the results suggest that the patient facing end of the interface is of a below average standard when looking at the benchmark standards for the system usability scale and the user experience questionnaire. This study recruited via a three-stage process (Figure 26) whereby participants had to complete two questionnaires prior to consenting to take part in the final user experience evaluation and response burden may have been quite high at this point which may have impacted the sample size. As detailed above, there were only three participants which may have affected the results of the SUS and the UEQ as they typically have a higher sample size when calculating the average scores. The entire process was conducted online due to the on-going covid-19 pandemic and to fit the context and time restraints of the PhD research at the time.

Despite the overall scores suggesting that it performed below average when compared to the benchmark standards, the patient facing front of the interface was rated positively across all subscales, particularly noting that the system was dependable and attractive. There were some mixed results about how easy the system was to use however it was noted that it seemed easy to learn. This part of the interface was designed purely to collect data from patients/service users and therefore is acting as an online questionnaire tool, but it was still important to test whether the interface actually worked and did what it was designed to do. From a user experience and data collection perspective there are no issues to address on this side of the interface to enhance a patients experience with using the interface.

There was a more than adequate sample size (n=5) for the first user experience evaluation which tested the ‘admin’ facing front of the interface. Therefore, the conclusions made from that study in terms of its quality and usability can be sustained. The second user experience evaluation looked at the patient facing front/online questionnaire, which recruited three participants. Although this number is slightly less, it was more

important to test the admin front as this would have the most significant impact on its intended use. It is anticipated that the low response to the second user experience study is due to response burden as it was the final stage of a three part study as explained in chapter 7. In order to gain a better insight into the user experience of patients using the T:POT interface a larger sample size would be needed or, a smaller qualitative study to better understand their experience. Based on the research conducted during this PhD prior to this study, the needs of patients usually centre around lower response burden, clear and simple to use and something that does what it is supposed to do. Therefore, the patient facing front of the interface is fit for purpose to conduct psychosocial evaluations of any current or future services provided by Tenovus Cancer Care.

The work undertaken in this chapter and across the thesis represents a successful application of a unique interdisciplinary approach. It demonstrates the blending of two separate disciplines that have triangulated to create and evaluate a final outcome. This phase assesses the core elements of the MRC framework by developing, refining, retesting and engaging with stakeholders in order to ensure the final product was fit for purpose. As with the previous study, this also represents that cyclical nature of Dewey's model of identifying a problem, reflecting and actioning.

Chapter Seven: Evaluation of the acceptability and effectiveness of T:POT in evaluating psychosocial support initiatives

This final empirical chapter reports on the final attempt to evaluate T:POT through an existing Tenovus psychosocial support initiative. The overall aim of this final study was to conduct a psychosocial evaluation of an existing Tenovus initiative to enable the piloting and evaluation of the Psychosocial Cancer Evaluation Toolkit and interface in a real-life setting. Prior to the COVID-19 pandemic, the specific objectives of this final study were to test the ability of T:POT to effectively evaluate a live psychosocial intervention within Tenovus through comparing two different interventions and collecting longitudinal outcome data; and to field test the acceptability and usability of the final system. As outlined in the introduction to this thesis, the COVID-19 pandemic had a significant impact on the direction of this research due to the impact on Tenovus Cancer Care. This final study underwent many revisions to attempt to achieve the original objectives but ultimately had to be reduced to reflect the reduced delivery within Tenovus Cancer Care and the time remaining for the PhD candidature.

The following chapter reports on the pilot study conducted to test the acceptability and feasibility of the T:POT with a cancer population. As outlined in Figure 27, this was the second study in a three stage process, with the first being a return to choir questionnaire and the third being the user experience evaluation reported in chapter 6. Therefore this chapter only reports on the second study.

The original aims of the PhD were achieved by developing the T:POT interface, as a reminder this is the Tenovus: Psychosocial Outcomes Toolkit and user-friendly data visualisation interface which was then to be used to evaluate the psychosocial impact of a Tenovus Cancer Care support service. All of the work completed up until now that is contained within the preceding chapters explains how these were developed in a parallel process, to be combined into one final working product. The overall aim of this final study

was to conduct a psychosocial evaluation of an existing Tenovus initiative to enable the piloting and evaluation of the Psychosocial Cancer Evaluation Toolkit and interface in a real-life setting. All of this work concludes the evaluation phase of this PhD.

Psychosocial support initiatives that were running within Tenovus in the first two years of this PhD included Activate Your Life, Sing With Us choirs, Support Line, and the Nurse-led call-back service. The researcher had also previously been involved in assisting with an evaluation of a previous initiative, the Tenovus Cancer Call-back Service, and at the time of the inception of the PhD there was no reason to suspect that Tenovus would cease to offer a variety of psychosocial support initiatives for those affected by cancer in Wales. Unfortunately, however, the unprecedented impact of the COVID-19 pandemic through 2019-2021 not only had huge repercussions for the ability of Tenovus to continue to fund psychosocial support initiatives, but also on this final stage of the PhD.

In early discussions with Tenovus prior to the pandemic, the agreed plan was to evaluate the 'Activate Your Life' (AYL) support service which provided structured psychosocial support to people affected by cancer. This would have been conducted longitudinally as AYL was a structured four-week course, so it allowed room for a baseline, weekly and follow-up evaluation. As has been discussed in some detail in the introduction to this thesis, Tenovus underwent many changes following the pandemic which meant that a lot of their psychosocial support services did not resume, and they were going to operate at a much more reduced capacity. After working with the research and insight team at Tenovus the only available plan remaining in December 2021 was to be able to conduct a smaller psychosocial evaluation on one of their remaining services, whilst also collecting some vital data for Tenovus. This vital data would allow them to understand service users' intentions of returning to in-person service provision following the pandemic and the transition from virtual service delivery back to in-person delivery,

bearing in mind that people with a cancer diagnosis were considered to be an extremely vulnerable and at-risk category throughout the duration of the pandemic.

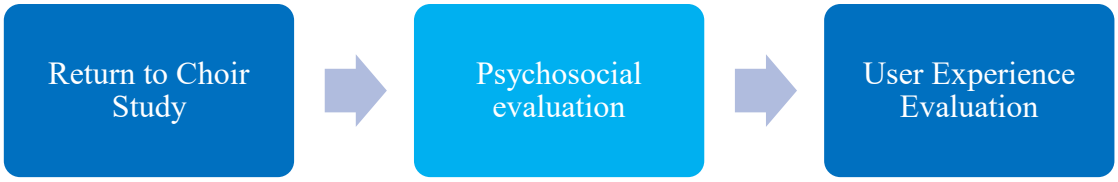
This led to an attempt to use T:POT to evaluate the impact of their Tenovus 'Sing With Us' choirs. The Tenovus 'Sing With Us' choirs are a community focused cancer support service set up by Tenovus Cancer Care and are conducted across 15 sites in Wales. The choirs are open to anyone who has a connection to cancer but are usually aimed at those who have either experienced cancer themselves or they support someone with cancer. The choirs have been a huge source of fundraising and awareness raising over the years as well as providing a psychosocial support service to people affected by cancer in Wales. The choirs are run by choir leaders who are all musical professionals, however there is no requirement to have any experience with music or singing to join a choir. They usually run once per week to rehearse for around 1.5 hours which is made up of actual rehearsal and social engagement with refreshments (Reagon et al., 2016; Tenovus Cancer Care n.d.)

The 'Sing With Us' choirs have previously been evaluated and evidence provided to support they improve psychosocial health outcomes, Reagon et al., (2016) conducted a longitudinal psychosocial evaluation of the Tenovus Sing With Us Choirs and measured health related quality of life and anxiety and depression. They found that people who had experienced a cancer diagnosis had improved health-related QoL and both those with cancer and those without had significantly less anxiety levels at each time point. They also found that depression scores did not change for either group at each time point. Additionally, through qualitative interviews and focus groups they added that the Sing With Us choirs provide feelings of belonging, social support, and interaction and generally just feelings of positivity. Following this, Fancourt et al., (2018) took this data and conducted an evaluation of psychosocial singing interventions for carers of people affected by cancer in London. They looked at mental health and wellbeing outcomes of people who

attended the choirs over the space of 24 weeks compared to a control group who did not attend the choirs. They found a significant decrease in anxiety levels over time and a significant increase in wellbeing over time, but no changes were found for depression, which supports the previous findings from data collected by Reagon et al., in 2016.

Figure 31

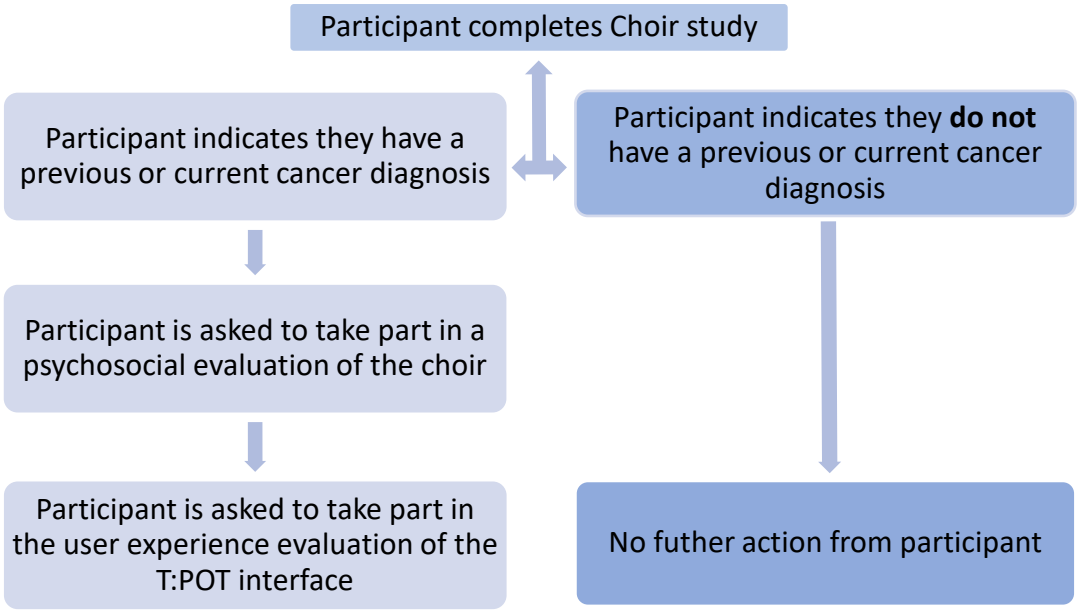
Visual representation of how the studies connected for the final evaluations, highlighting the stage reported in this chapter



Whilst some adaptations had to be made due to the COVID-19 crisis and changes within Tenovus in relation to their psychosocial support provision, the study reported in this chapter allowed the planned aims of the KESS studentship to be met, but importantly, the application of elements of the psychosocial evaluation toolkit to understanding the current psychosocial needs of people with cancer who use services provided by Tenovus. This study was conducted as part of a collaboration with the research insight team at Tenovus who were interested in finding out how people felt about returning to face-to-face choir practice following the final easing of covid-19 restrictions and given the time restraints for the remainder of the PhD it seemed logical to combine these studies to maximise the chances of recruitment. Figure 32 shows the pathway that a participant would take in order to complete the return to choir study and the choir evaluation, it is important to note that the data collected for the return to choir study will not be reported in this thesis as this was collected on behalf of Tenovus Cancer Care's research insight team and the data collected from a participant who completed both studies was not linked together and therefore had no relevance to report.

Figure 32

Participant recruitment pathway depending on cancer status



A diagnosis of cancer and its associated treatments is significant life event often resulting in acute stress and significant life change that can last many years after initial diagnosis (Deimling et al., 2006; Guner et al., 2006). The decline in health, side effects of cancer treatment, worries about death and dying and changes in relationships all contribute to the heightened level of strain and reduced quality of life following a diagnosis. The need for psychosocial interventions to support individuals through the initial diagnosis and beyond is well recognized and evident in the number of cancer support organisations offering a range of psychosocial support to individuals affected by cancer and their family members.

As this study was conducted during the latter stages of the pandemic, it is important to note that the covid-19 lockdown measures had a dramatic impact on cancer care. Routine screening, some treatments and support were all suspended until further notice (Blood Cancer UK, 2020). The full impact of COVID-19 on people affected by cancer is not yet clear, however with a lack of screening, urgent referrals, surgeries, and treatments being halted or delayed, it is predicted that there will be a severe long-term impact (CRUK, 2020).

Individuals with cancer, who have received specific cancer treatments potentially have an increased susceptibility of contracting and suffering great consequences of covid-19 (Guan et al., 2019; Liang et al., 2020; UKCCMP, 2020). In order to manage this risk, the government guidelines for people with cancer, or who have undergone specific cancer treatment, were advised to undertake shielding measures during the covid-19 pandemic whereby they are not to leave their houses at all and avoid contact with other people in order to lower their risk of contracting the virus. (UKGov, 2020; NHS England, 2020), this advice was in place from March to August 2020 when the shielding advice was placed on 'pause' (UK Gov, 2020), such restrictions were in place on and off for a period of two years. During this period the NHS aimed to continue essential and urgent cancer treatments, which were treated on a case-by-case basis depending on levels of vulnerability. The creation of 'cancer hubs' were implemented in London, creating a safer space away from the hospital environment to allow the safe delivery of cancer treatment (Tenovus, 2020; UK Gov, 2020). However, during this time in Wales, these 'cancer hubs' did not yet exist, therefore leaving cancer patients without access to safe treatments. It is estimated that only around one quarter of urgent referrals were being dealt with in Wales during this period (BBC, 2020).

As well as potentially experiencing an increase in levels of isolation and loneliness due to the lockdown restrictions, individuals with cancer also fell into the "vulnerable" group that also required them to follow shielding advice. As well as having to manage the amount of information being communicated daily which may be overwhelming and stress-inducing for some individuals (Anxiety UK), individuals with cancer also had to understand and accept the current changes to their clinical care with all the anxiety and confusion that may cause (CRUK, 2020). Advice from Ovarian Cancer Action (OCA, 2020) recommended that should individuals find that they are becoming overwhelmed with the information they were being communicated daily they should; limit the time spent looking at covid-19 related information and when they did engage they should ensure they are accessing information

from credible sources; engage in some self-care activities such as meditation, yoga, and plentiful sleep; and stay connected with friends and family through virtual means. The current study aimed to explore the impact of a psychosocial singing intervention for people affected by cancer by trialling the T:POT interface to measure key psychosocial health outcomes identified throughout the thesis.

Aim

The aim of this study was to trial the T:POT interface by conducting a live psychosocial evaluation of the of the Tenovus 'Sing With Us' choir on people who had experienced a cancer diagnosis.

Method

This study was developed in partnership with Tenovus Cancer Care who were interested in finding out how their choir members felt about transitioning from virtual choirs and returning to in-person choir practice following the end of the COVID-19 lockdown restrictions. Following this, those who had experienced a cancer diagnosis were invited to take part in a psychosocial evaluation of the 'Sing With Us' choir. Using Qualtrics online survey platform for the 'Return to Choir' study and using the Tenovus: Psychosocial Outcomes Toolkit (T:POT) interface to conduct the psychosocial evaluation. Full ethical approval for this study was granted by the UWTSD ethics committee on 17/09/2018 (see appendix A for approved ethics form and Appendix E for study materials).

Participants

This study aimed to recruit individuals over the age of 18 who had experienced a cancer diagnosis and had been a member of or, had used the Tenovus Cancer Care 'Sing With Us' Choir'. Figure 32 depicts the participant pathway and inclusion criteria for this study. Participants were recruited via Tenovus Cancer Care's public social media platforms

and private Facebook groups ran by choir leaders that were specifically for choir members (See appendix F for study advert and information sheet and associated materials).

Design

This study employed an online mixed methods approach, using validated quantitative measures (T:POT) and qualitative free text data. Data was collected at one time point and data collection ran for a period of four weeks in November 2021.

Measures

The Tenovus: Psychosocial Outcomes Toolkit (T:POT) was used to evaluate the psychosocial impact of the 'Sing With Us' choirs. The development of the T:POT has been well documented throughout this thesis and a summary of each of the validated measures and overall outcomes being measured are summarised below and further detail can be found in Chapter four and six, and the full toolkit in Appendix F.

Unmet Needs: The *Survivor Unmet Needs Survey – Short form* (SUNS-SF; Campbell et al., 2014), a 30-item scale consisting of four subscales measuring: *information, financial concerns, access and continuity of care* and *relationships and emotional health* which all contribute to the overall measurement of unmet needs in a general cancer population.

Quality of Life: The *Functional Assessment for Cancer Therapy – General* (FACT-G; Cella & Tuskey, 1993). This is a 33-item questionnaire measuring overall quality of life in a general cancer population through five subscales including *physical, functional, social, emotional* and *relationship with doctor.* An individual is given a score for each subscale and a total score to indicate overall quality of life.

Loneliness: The *Cancer Loneliness Scale* (CLS; Adams et al., 2017) will be used as a predictor variable and is a 7-item unidimensional scale measuring loneliness following a

cancer diagnosis. This scale specifically focuses on how often individuals feel lonely, or isolated at different points of their cancer journey and is considered a key variable to include given the timing of this study being after the end of the final lockdown.

Fear of recurrence: *Fear of Cancer Recurrence Inventory* (FCRI; Simard & Savard, 2007), a 43-item scale consisting of seven subscales measuring: *triggers, severity, psychological distress, coping strategies, functioning impairments, insight, and reassurance*. This scale specifically focuses on the fear associated with a cancer diagnosis returning following treatment.

Free text data

Participants were offered the chance to add anything in at the end of the study that they felt was relevant. The use of free text data is well supported, and it is thought that it offers a narrative that self-reported Likert scale style questionnaires do not and can offer an insight into a participants experience that may have otherwise been missed (Rich et al., 2013).

Materials

The materials required for this study centred around the Tenovus: Psychosocial Outcomes Toolkit (T:POT) interface with the addition of Qualtrics online survey platform for the purpose of recruitment to the return to choir study that led participants into the choir evaluation. The study was conducted online, and no physical materials were required which was decided to be the most efficient way of conducting the entire study considering the first part was focusing on returning to face-to-face contact. The development of the T:POT interface has been discussed in detail in Chapter six, but it will be summarised here as a reminder.

Tenovus: Psychosocial Outcomes Toolkit (T:POT) interface

The T:POT interface is a psychosocial toolkit of validated psychometric questionnaire measures (detailed above in the measures section) contained within a user-friendly data visualisation interface. The interface is designed to collect and analyse data through the validated questionnaires and produce easy to read results. The interface has been designed and evaluated to ensure that any member of staff at Tenovus Cancer Care would be able to use it to its full potential. With the interface having undergone extensive user experience testing it was important then to ensure the validated psychological scales embedded within it were fully tested. The T:POT interface is designed to combine the four questionnaires into one long questionnaire and a link is generated in order to send out to participants. An important element of the T:POT interface is the 'Live Data' page which provides all of the user-friendly graphs to show the results of the data that has been collected and a unique element of this is that it is updated immediately after a questionnaire has been completed. This means that for the research and insight team at Tenovus, they are always looking at the most up to date data and getting real-time information.

Procedure

Participants were recruited via Tenovus Cancer Care and their social media platforms. The target audience for the Return to Choir study was anyone who was a current choir member of which people did not need to have had a cancer diagnosis. For the choir evaluation only those who had experienced cancer themselves either now or in the past were invited to take part in the study. Figure 32 depicts the pathway taken for a participant

depending on if they have indicated whether they had a cancer diagnosis (now or in the past) or not. If a participant indicated, they had a cancer diagnosis (now or in the past) they were directed to the information sheet for the choir evaluation following their completion of the return to choir questions. Participants were fully informed of the study and were asked to complete a consent form prior to taking part. Participants completed the psychosocial evaluation measures through the T:POT interface by clicking on a URL that was located in the debrief form of the 'return to choir study and were fully debriefed at the end of the study. The information preceding the questionnaires and the timing they were being asked to reflect on were anchored towards 'since you received support or engaged with a Tenovus Cancer Care support service'. This ensured participants were thinking specifically about the support they may have received from Tenovus when thinking about their unmet needs, loneliness, quality of life and fear of recurrence. This is important to note as each questionnaire had its own timeline for the participant to think about (e.g., in the last month, in the last week) and it was important to ensure they were anchored towards the choir as data was only being collected at one time point.

Results

This section will detail the results of this study which were generated through the T:POT interface and graphs will be drawn directly from the purpose built 'Live Data' page within the interface. It is important to note that participant recruitment was very limited due to being part of a larger recruitment pathway and relying on those who had taken part in the 'return to choir' study to consider taking part in the psychosocial evaluation of the choirs. It was noted by Tenovus that recruitment may not be that high due to a large proportion of Choir users having not experienced a cancer diagnosis themselves.

A total of five participants (four females, one male) with a mean age of 68 (M=68, SD=8.50) completed the psychosocial evaluation of the Tenovus 'Sing With Us' choir

using the T:POT interface. Participants all had a previous or current cancer diagnosis and were current members of the Tenovus Cancer Care 'Sing With Us' choirs. The study explored levels of unmet needs, quality of life, loneliness and fear of recurrence using the specifically developed Tenovus: Psychosocial Outcomes Toolkit interface. Participants completed four validated questionnaires that are described in more detail earlier in this chapter but as a reminder they are the Functional Assessment for Cancer Therapy – General (FACT-G), Supportive Unmet Needs Survey – Short Form (SUNS-SF), Cancer Loneliness Scale (CLS) and the Fear of Cancer Recurrence (FCR) and together they make the Tenovus Psychosocial Outcomes Toolkit (T:POT) measuring unmet needs, quality of life, loneliness and fear of recurrence. Each of these psychosocial outcomes are reported below, nothing that data was collected at one time point as a baseline measure.

Table 41 *Overall scores across all outcomes*

	N	Range	Minimum	Maximum	Mean	Std. Deviation	Variance
Quality of Life	5	20.30	74.20	94.50	80.52	8.69	75.602
Unmet Needs	5	20.33	14.00	34.33	25.86	7.46	55.731
Loneliness	5	14.00	3.00	17.00	9.80	6.53	42.700
Fear of cancer recurrence	5	49.00	26.00	75.00	45.0	20.13	405.500

With the exception of Quality of life (where higher scores equate to better quality of life), higher scores indicate worse results for unmet needs, loneliness and fear of cancer recurrence. Quality of life scores amongst participants are quite high indicating good quality of life. Unmet needs amongst participants are quite high indicating that there is some level of unmet needs amongst participants. Overall scores for loneliness and fear of cancer recurrence do not indicate a high level of concern amongst participants, there is a medium level of loneliness and fear of cancer recurrence present. Each scale and its subscale scores (if relevant) are reported in more detail below.

Table 42

Quality of life (FACT-G)

	N	Range	Minimum	Maximum	Mean	Std. Deviation	Variance
Overall QoL	5	20.30	74.20	94.50	80.52	8.69	75.602
Physical Wellbeing	5	13.00	14.00	27.00	21.50	5.50	30.250
Social/Family Wellbeing	5	15.20	10.00	25.20	19.30	6.85	46.937
Emotional Wellbeing	5	7.00	17.50	24.50	20.72	2.68	7.198
Functional Wellbeing	5	12.00	14.00	26.00	19.00	5.65	32.000

The FACT-G measured overall quality of life and four subscales depicting separate domains of quality of life. Overall QoL scores were quite high with a mean score of 80.52 (SD=8.69) reflecting that this group had high level of QoL. Functional wellbeing (M=19.0, SD=5.65) and Social/Family wellbeing (M=19.30, SD=6.85) scored lower than Emotional (M=20.72, SD=2.68) and Physical Wellbeing (M=21.50, SD=5.50). Functional wellbeing concerns itself with the ability to work, how well they sleep and to what extent they are content and enjoying life, and social/family wellbeing concerns itself with how much support they feel they get from their family and friends.

Table 43

Unmet needs (SUNS-SF)

	N	Range	Minimum	Maximum	Mean	Std. Deviation	Variance
Overall unmet needs	5	20.33	14.00	34.33	25.86	7.46	55.731
Information	5	2.33	4.67	7.00	6.06	1.27	1.633
Work and financial	5	.00	.00	.00	.00	.00	.000
Continuity of care	5	11.67	.00	11.67	6.53	4.28	18.402
Coping	5	13.35	2.80	16.15	8.48	4.83	23.377

The Survivor Unmet Needs Survey – Short Form (SUNS-SF) measures a range of unmet needs in a cancer population. The anchoring of this questionnaire asked participants to reflect on their level of unmet needs across each domain since they had received support

or engaged with a service provided by Tenovus Cancer Care. The levels of unmet needs across all domains were considered ‘very high’. Unmet coping needs (M=8.48, SD=4.83) were the highest amongst participants, this domain concerns itself with unmet coping, sharing and emotional needs that relate to their relationship with others and their emotional health.

Table 44

Loneliness (CLS)

	N	Range	Minimum	Maximum	Mean	Std. Deviation	Variance
Overall loneliness	5	14.00	3.00	17.00	9.80	6.53	42.700

The Cancer Loneliness Scale (CLS) measured overall levels of loneliness since participants had received support or engaged with a service provided by Tenovus Cancer Care. Overall levels of loneliness were reasonably low (M=9.80, SD=6.53). The maximum possible score on the cancer loneliness scale was 28 and higher scores indicate higher levels of loneliness. The highest score in this study was 17 and therefore indicated loneliness levels were low to medium.

Table 45

Fear of cancer recurrence (FCR)

	N	Range	Minimum	Maximum	Mean	Std. Deviation	Variance
Overall FCR	5	49.00	26.00	75.00	45.00	20.13	405.500
Triggers	5	11.00	5.00	16.00	9.40	4.15	17.300
Severity	5	20.00	7.00	27.00	16.00	8.18	67.000
Psychological distress	5	11.00	.00	11.00	3.60	4.27	18.300
Functioning impairments	5	8.00	.00	8.00	4.40	3.78	14.300
Insight	5	.00	.00	.00	.00	.000	.000
Reassurance	5	6.00	2.00	8.00	3.60	2.60	6.800
Coping strategies	5	12.00	.00	12.00	8.00	5.04	25.500

The Fear of Cancer Recurrence (FCR) measured domains related to the worry and fear of an individual's cancer recurring or a new cancer forming. None of the seven domains recorded any high levels of concern amongst participants.

Free text

Only two participants (n=5) completed the free text box asking for any additional information they would like to add to their data.

"A friendly group of people who know how to treat you"

"I absolutely love Tenovus…"

Both comments were positive feedback commending Tenovus Cancer Care and the choir groups and one highlighted that they would like to see more involvement from Tenovus with other cancer specific charities or awareness raising as they felt the focus, especially through the choir fundraising was on breast cancer for the majority of time.

Discussion

Whilst some adaptations had to be made due to the COVID-19 crisis and changes within Tenovus in relation to their psychosocial support provision, the study reported in this chapter allowed the planned aims of the KESS studentship to be met, but importantly, the application of elements of the psychosocial evaluation toolkit to understanding the current psychosocial needs of people with cancer who use services provided by Tenovus. This study was conducted as part of a collaboration with the research insight team at Tenovus who were interested in finding out how people felt about returning to face-to-face choir practice following the final easing of covid-19 restrictions and given the time restraints for the remainder of the PhD it seemed logical to combine these studies to maximise the chances of recruitment

The aim of this study was to trial the use of the Tenovus: Psychosocial Outcomes Toolkit (T:POT) interface to conduct a psychosocial evaluation of the Tenovus Cancer Care 'Sing With Us' choirs. The T:POT measures consisted of the Functional Assessment of Cancer Therapy- General (FACT-G), Survivor Unmet Needs Survey – Short form (SUNS-SF), the Cancer Loneliness Scale (CLS) and the Fear of Cancer Recurrence (FCR) which overall measured quality of life, unmet needs, loneliness, and the fear of cancer recurring. The constructs and domains contained within these measures that were highlighted as important and relevant in the Delphi study are contained in chapter five.

The results of this study are supported by the literature discussed in detail in Chapter 2 detailing the psychosocial impact of a cancer diagnosis. Niedzwiedz et al., (2019) highlights that a cancer diagnosis in general can have a substantial impact on mental health and well-being, and often patients are unaware of when they may need support which can often lead to

a level of unmet needs (Lang-Rollin et al., 2018) which were reported in this study. Participants in this study had a high level of unmet needs, specifically with how well they were coping. Given that this study was conducted as the UK was approaching the end of the final lockdown restrictions, it may support the fact that those people were not having their needs met due to a lack of service or support. The impact of the pandemic on people affected by cancer meant that their usual care was disrupted, in addition to the delays in diagnosis and treatments which may explain their high levels of unmet coping needs. However, as has been highlighted in the literature (Lang-Rollin et al., 2018; Niedzwiedz et al., 2019; Mlakar et al., 2021) unmet needs are a common factor of a cancer diagnosis and the recommendation for continually assessing these needs is supported by Mirosevic et al., 2019. The use of the T:POT would facilitate the continual assessment of these needs using the same outcome measure each time which would allow for a direct comparison between each time point.

As previously discussed in regard to collecting data at more than one time point, the previous research conducted specifically evaluating the Tenovus Sing With Us choir and psychosocial singing interventions (Reagon, 2016; Fancourt, 2018) were conducted longitudinally and data was collected at multiple time points which allowed them to assess changes over time and report improvements in health outcomes. This study found very good levels of quality of life amongst participants but very high unmet needs, specifically those related to how well they were coping. Loneliness related to their cancer was relatively low along with their fear of cancer recurrence. Data was collected at one time point and participants were asked to think about their answers in relation to the support they had received or services they had engaged with from Tenovus Cancer Care. Due to not having a control or comparison group or the ability to collect data at multiple time points, there are no

significant conclusions to be drawn. The literature supports that the psychosocial impact of a cancer diagnosis can change throughout the trajectory and being able to assess this at multiple time points gives a better representation of the impact of a diagnosis and how people cope (Hamilton et al., 2018; Andrykowski et al., 2008). This study does well to evaluate the psychosocial health of those people who had used the choir, but it is not possible to attribute sole cause to the choir intervention itself. However, given that the choir is designed to encourage social interaction and engagement, and that previous research has supported the improvement of health-related quality of life in psychosocial singing interventions (Reagon et al., 2016; Fancourt at al., 2018), it is evident that those who use the choir do have less feelings of loneliness and very good self-reported quality of life. Further support for music or creative related interventions is highlighted in a systematic review of interventions by Teo et al., (2018) who reported that music therapy interventions showed positive results in relation to quality of life and a reduction in levels of anxiety and depression. Participants in this study who had engaged with the choir service reported good levels of quality of life overall.

Participants reported low levels of fear of cancer recurrence, it is not known what type of cancer or which part of the cancer trajectory that participants were at. This is something that would be beneficial to collect in future, however the initial plan for the T:POT was that it would link into the existing client management system at Tenovus Cancer Care to reduce the question burden on people affected by cancer so it was decided that this information would not be collected on this occasion. By knowing the type of cancer or when they were diagnosed it may have been easier to draw conclusions as to why their fears about cancer recurrence were so low.

Following the results of this study, although low in attrition, it can be seen that the measures do in fact capture a snapshot of how an individual's coping response may have impacted their psychosocial outcomes. This study reported high levels of unmet needs in the coping subscale of the SF-SUNS. This is notable due to the discussion throughout this thesis regarding the efficacy of coping measurement. The coping subscale reported the highest unmet needs out of the whole scale, which would depict that those individuals are either not coping, or they are not being provided with what they need in order to cope well. The critique around measuring coping has been discussed in depth as there are so many factors to consider. The SF-SUNS coping subscale tries to capture a lot of these factors with one question per element. Coping is too complex to be captured in one subscale, however this data shows that there are many needs related to how people are coping, which can be examined and supported.

When considering this finding within the SRM framework, the coping subscale does not infer anything about the coping response, or coping attempt, it only describes what may be needed in order to for an individual to feel like they are coping. Additional points to note are that the results from the FACT-G indicated high levels of quality of life amongst participants. When the coping subscale within the SF-SUNS is removed the results from this study indicate that participants feel they have a good quality of life, low levels of worry or concern about recurrence, and do not feel particularly lonely. This could subjectively suggest that these individuals are coping well with their cancer following engagement with a Tenovus cancer support service as per the anchoring of the questions. Interestingly, drawing back to the earlier critique from Obbarius et al. (2021), who also removed coping when testing their model and found their model performed better. Although T:POT is not a framework and not a model, it should be considered that in order to demonstrate how an individual may be coping with their

cancer, any subscale or measure related to trying to measure 'coping' specifically, should be removed. By removing an attempt to measure coping it may allow psychosocial health outcomes to become the focus, which may then help demonstrate the extent to which someone may be coping, based on whether their outcomes have improved. There is definitely a role for measuring levels of unmet needs as this would be valuable information to feedback into a cancer support service, but measuring unmet coping needs may not be the most effective element to include.

There were only five participants who took part in this study, this is a very low and disappointing number for a psychosocial evaluation, however there was little control over the recruitment to the study and due to the time constraints and the ongoing impact of the COVID-19 pandemic, this is the optimal outcome. Due to the nature of the T:POT interface it is not known how many people may have started the study and then stopped due which could be attributed to response burden given the T:POT is over 100 questions long. The lack of patient involvement in choosing, or reviewing the measures is emergent here. Perhaps a level of involvement in this phase could have improved attrition rates. However given the additional challenges surrounding recruitment, and research fatigue following the pandemic, it is not surprising that the response rate was so low. Despite this, enough data was collected to demonstrate its usability within the cancer field as the participants who completed the questionnaires were all people with cancer and did not report any issues or difficulty with the questionnaires. This provides enough rationale to conduct a larger pilot to conduct reliability and validity analysis on the identified measures. It is hoped that this acted as a sufficient enough pilot to demonstrate its feasibility and usability for Tenovus Cancer Care.

Whilst clearly limited in terms of both data and methodological robustness, the data reported here suggest that the initiatives that Tenovus offer are helping address the unmet support needs of individuals affected by cancer, particularly in relation to quality of life, unmet needs, loneliness and fear of recurrence. However, it is not possible to clearly state to what extent these initiatives improve key psychosocial outcomes from this study alone.

Conclusion

This chapter represents the aligning of the theoretical framework of how to understand how people cope with stress, and the MRC framework that tells us how to robustly develop and evaluate complex interventions that have been designed to support those individuals. It is difficult to draw clear conclusions on the efficacy, reliability and validity of T:POT due to the low attrition. Despite the lack of data within this chapter for the reasons stated, it still represents the research process from creation to inception. This phase of the research was always intended to be a large scale psychosocial evaluation to test the T:POT interface and evaluate a service provided by Tenovus, but by still being able to carry out a smaller, pilot study, this fits with the process outlined in the MRC framework and with the overall aims of the PhD itself. In summary, the findings from this study suggest that T:POT may be a useful and acceptable tool with which to capture data on the psychosocial health of individuals affected by cancer. Future studies would need to gain stronger data to continue to build the evidence base for T;POT. There is no reason that T:POT could not be adapted to also be of use to other health conditions or other organisations providing cancer support. The framework identified through this process could be replicated and applied to many other contexts, with an ongoing potential for adaptation and usability.

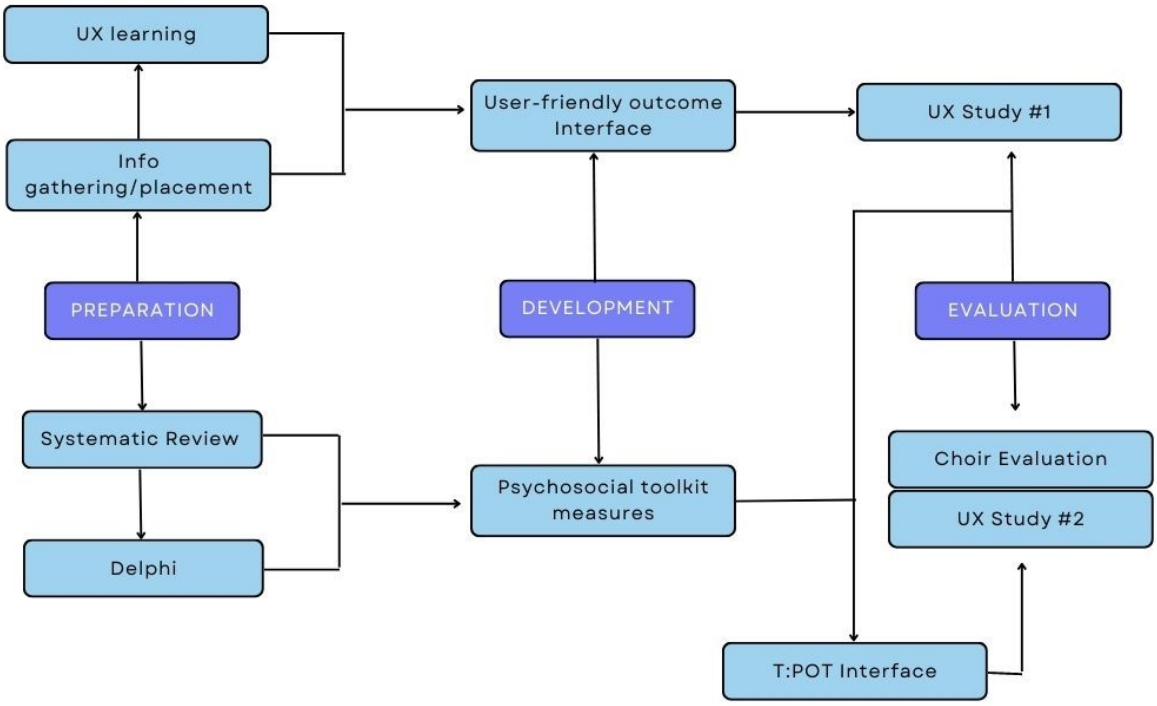
Chapter Eight: General Discussion

This final chapter will draw together the various phases of research described in the previous chapters and critically consider the unique contribution to knowledge demonstrated through the research contained within this thesis. It will include a section on the researcher's critical reflections of the entire PhD process, including (but not exclusively focusing) on a discussion of the impact of the covid-19 pandemic on the research process and the unintended evolution of the original thesis plan. The chapter will start with a brief re-cap of the aims of the thesis and a summary of the key findings across the thesis. It will review the overall theoretical and methodological approach to the thesis, including the framework for the development and evaluation of the final interface (T:POT). It will then critically consider the implications of the research for the field of psycho-oncology with particular consideration given to the implications for third sector and voluntary sector organisations offering psychosocial care and support to individuals affected by cancer and their families across the UK.

This thesis had the following two main aims, working in partnership with Tenovus Cancer Care as part of a KESS-II funded PhD studentship: firstly, to identify, quantify and map core patient reported outcomes for psychosocial cancer initiatives and secondly, to develop and evaluate the utility of a bespoke computer interface offering a user-friendly interface. Both of these broad aims were met over the course of the body of work presented within this thesis, with the process of preparation, development and evaluation demonstrated in Figure 5 and as referenced throughout the entirety of this thesis.

Figure 5

An overview of how the thesis elements interconnect



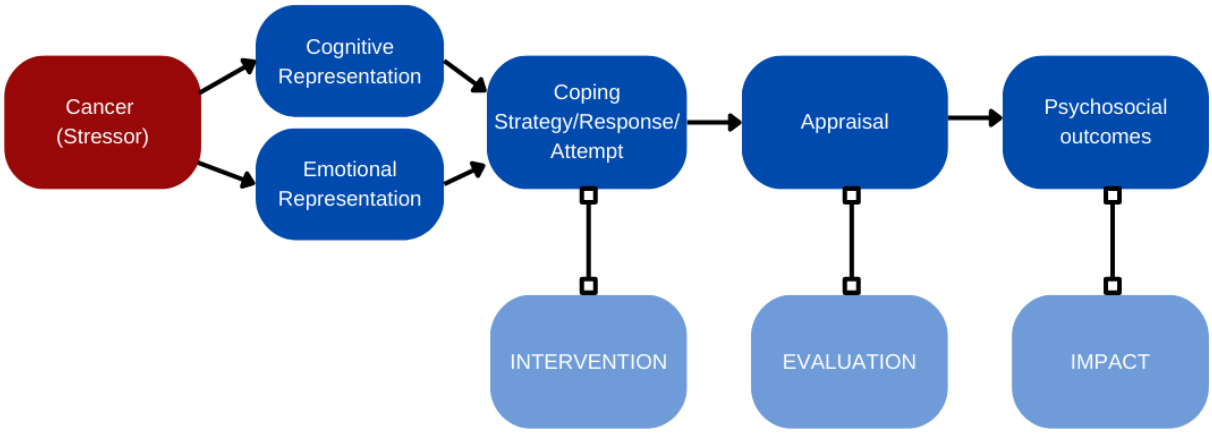
The initial psychosocial toolkit was developed through two key elements of the research. The systematic review reported in chapter four, of patient reported outcome measures validated for use on a general cancer population, and the online modified Delphi study reported in chapter five, exploring expert consensus on the relevance and importance of the constructs contained within the outcome measures identified in the systematic review. Whilst these studies were underway, the parallel development of the computer interface began, working with academic and industry experts in the field of user experience (UX) design, documented in chapter six. This dual process of research into the most relevant PROMS alongside the initial computer interface design culminated in the development of the Tenovus:

Psychosocial Outcomes Toolkit (T:POT) interface, a bespoke computer database specifically designed for Tenovus Cancer Care to enable them to evaluate the impact of their cancer support initiatives and to provide user-friendly effective data visualisation outputs. The acceptability and potential effectiveness of T:POT was then evaluated using a range of participant groups in Chapters Six and Seven. This process provided a feedback loop which allowed adaptations to be made to the interface prior to the final evaluation. Due to the COVID-19 pandemic and associated restrictions throughout 2020-2022, these studies were conducted online, and the final study became a smaller scale study than originally hoped in order to fit the timescales of the PhD and the post-pandemic position of Tenovus Cancer Care.

As documented previously in this thesis, two key theoretical perspectives underpinned the body of research presented. Both of which provide insight into the psychological mechanisms that drive forward people's coping efforts when faced with a cancer-related threat or stressor. Whilst Lazarus and Folkman's theory of stress and coping (1984) provided the broad theoretical lens through which to understand the patient journey through a cancer diagnosis, it was Leventhal's Self-Regulation model (1980) that was able to be explicitly mapped to a number of constructs and processes contained within this thesis, as shown Figure 33 below.

Figure 33

The overlap between the SRM and T:POT



Chapter two provided a detailed critical review about the role of coping and how it is measured, and the limitations identified through this review then informed the approach to creating a psychometrically robust, consensus based, and unique toolkit and research outcomes interface. The framework identified within this thesis supports that the coping process is demonstrated by examining changes in self-reported psychosocial health outcomes. Current literature increasingly talks about individuals being common sense scientists and the experts of their own cognitive and emotional representations (Leventhal, 1980; Benyamini & Karademas 2019; Haggar & Orbell, 2021). Therefore, it makes sense that they should then be the experts in appraising these outcomes and demonstrating that through their psychosocial health outcomes. The SRM relies on an individual appraising a health threat and PROMS rely on the ability to self-report, self-assess and appraise their needs, emotions and behaviours. All these subsequently demonstrate a coping response. In this body of work it is recognised that illness representations play a valuable role to understanding the cognitions underpinning coping efforts and outcomes, however it was not a focus of the current toolkit.

There has been discussion throughout of how the measures identified and selected for T:POT overlap with the constructs within the SRM and the overall importance of evaluating outcomes as it represents that role of appraisal. By undergoing the process of mapping the measures across the SRM, it is evidence that PROMS play a role in self-assessment, and although individuals are considered to be the experts of their own cognitive and emotional representations, perhaps this infers that PROMS help to encourage the processes around this. The framework identified within this body of work can be replicated and refined to enhance the measures that are contained within T:POT.

Patient reported outcomes for psychosocial cancer initiatives

The identification, quantification, and mapping of a core set of patient-reported outcome measures (the psychosocial toolkit) formed the critical bases for the entire thesis. The key health outcomes identified as important and relevant which were then mapped across the outcome measures that had been identified, covered quality of life, unmet needs, cancer related loneliness and fear of cancer recurrence. The identification of these outcomes as research priorities are supported by work conducted by Boundouki et al., (2019), Jarett et al., (2013) and earlier work from Corner et al., (2008) who all identified quality of life as a key indicator and top research priority, next to unmet needs, fear and distress. As discussed in Chapter 2, the term distress is a generic term used to encompass all emotions related to depression, anxiety, fear, worry and panic (Kirk et al., 2021) which are all measured within the final toolkit.

The final toolkit was developed through triangulating the results of the initial systematic review and the Delphi consensus study which is a method that is supported and guided by Green et al., (1989) model and Noble and Heale's (2019) guidance of using

triangulation in research to increase credibility of the findings. As discussed in the methodology section of this thesis, the importance of triangulation for this research meant that by combining these methods and outcomes together it allowed the credibility and validity of the results to be strengthened. There are multiple strands of triangulation and for this research, methodological triangulation was used to allow multiple methods of data collection to be used in order to create something credible. The notion of triangulation in any of its methodological approaches is that it allows the validation of where findings are the same. The results of the systematic review may have highlighted a number of measures, however what came from this which crossed over with the Delphi findings were that people affected by cancer felt these constructs were important and relevant to ask about, people were given an opportunity to add constructs in that may have been missed and this only yielded an additional three constructs. This tells us that combining these methods and these findings adds that level of credibility and validity.

The decision was made following an initial scoping review of PROMS to only focus on PROMS that had been validated on a cancer population. The rationale for this was that the methodological quality assessment would be higher if they were developed and validated on the target population, and it therefore allowed the review to be more focused. In hindsight however, this meant that many of the most commonly used PROMS reported in psychosocial outcome studies in cancer populations (e.g., HADS, PANAS, IPQ) were not included in the systematic review and therefore not considered for inclusion in the final toolkit or T:POT interface. Another reason for focusing specifically on measures that had been validated on a cancer population reverts back to one of the original justifications for this research, the field of psychosocial oncology or even psychosocial intervention evaluation is saturated with outcome measures to the point where there is no way to directly compare outcomes against each other

or ensure their methodological quality for the target population. For this research Tenovus Cancer Care needed a way of being able to compare their services against each other using the same outcomes, therefore those outcomes needed to be specific to a general cancer population, thus not seeing the justification for a much bigger pool of outcome measures to be considered. As previously noted in hindsight perhaps including those more commonly used, but not cancer population specific measures would have added more depth and credibility to the toolkit, but the measures identified still line up with the constructs that people felt were important and relevant to measure and achieved the desired outcomes for this research.

Engaging with key stakeholders and experts was considered a priority in the early stages of planning this thesis (cReST, 2022; Kearney et al., 2017; . Critically, the definition of experts within this the first phase of the PhD was extended to include anyone who had a personal or professional connection to cancer. This included but was not limited to patients, service users, and family/carers, professional and volunteer roles. This was in order to obtain as wide a pool as possible in terms of the cancer experience. This in line with recent calls to further involve the public in research, intervention, and service development which for the cancer population was documented in the Cancer Delivery Plan for Wales (2016-2020) and is something that charities including Tenovus Cancer Care value and practice in their service provision. There is a growing recognition for patient representatives and the value they bring to the experience of the target population, this is increasingly a role that has been made more official over the last few years that creates a value for people to feel that their involvement is of an equal stature to those of the 'professional experts'.

For this research the plan was to try and engage with people affected by cancer at every stage which in hindsight was not done as effectively as it could have been. The main area of engagement with people affected by cancer was during the Delphi consensus study

(Chapter 5), the main purpose of this study was to take everything that had been concluded from the systematic review and invite the people that had been defined as experts for this research to analyse these findings and to triangulate some further and final findings. For the Delphi study, there were four categories of 'expert' recruited for this study with the highest proportion (n=33/48) indicating they had experienced a cancer diagnosis. People were able to select more than one expert status which meant that people who had indicated they had a cancer diagnosis, may have also held another expert role. The study was not set up to be able to define a primary and secondary expert role and in hindsight this may have provided more context by being able to quantify that secondary role. Despite this a good range of experts from the public took part in this research and it was felt that there was enough representation of expertise to create the expert panel. The Delphi method is a highly effective way of engaging a range of people on a large scale, for this study it was conducted online making it an E-Delphi or modified Delphi. This study was conducted prior to the COVID-19 pandemic so it did not require any adaptations to be conducted online as this was always the plan. An important part of a Delphi study is ensuring anonymity and by conducting it online this helps to ensure that level of anonymity and therefore if it were to be conducted again or if this method was to be used again in the future, then it would still be better to do this online. The difficulty with any research method but especially with the Delphi method is the level of attrition which is highly common in Delphi studies as the same people are needed for multiple rounds of aggregation. This was something that there was an awareness of at the time of planning and it was hoped that a two round Delphi was enough to reach consensus on these items. Two rounds worked well for this study, agreement on the level of importance and relevance for a lot of the constructs was reached in round one and then round two further strengthened these results.

The results of the Delphi study contained within this thesis doesn't offer any evidence that there was a difference in the opinion between the expert categories as this is not something that was able to be separated out after the fact. In hindsight as mentioned above, it would have been useful to have allowed participants to select a primary and secondary expert status which would have allowed the separation of this to explore whether those who chose to identify as an expert who had experienced cancer themselves would differ from those who were clinical or academic professionals. Despite the lack of evidence to support the involvement of people affected by cancer, it still adds to the triangulation of the results between the systematic review and the Delphi study to create a toolkit that has been informed by and developed for people who have experienced a cancer diagnosis. Future research should continue to involve the public or target population in their research and perhaps ensure there is a way of evaluating the benefit of doing so.

General methodological considerations

During the planning stages of this PhD, it was intended to involve patients and stakeholders at every given opportunity by developing a project steering group. A small steering group was put together at the beginning of this research with the intention of this being something that was utilised for each phase of the research due to the applied nature of the research as it was felt this would be beneficial to the overall process. The steering group was utilised somewhat during the Delphi planning stages but it didn't really garner enough support to keep it going. The steering group never progressed into developing an official process of meeting and reviewing and perhaps having something more structured that was engaged with on a regular basis would have allowed this to be more beneficial to the research development. A project steering group would have also allowed for the involvement of patient

representatives which when putting together the group it proved difficult to recruit one. In hindsight, a more formal process of developing a steering group could have been followed. Despite this, the Delphi study, the interface development, and subsequent user testing involved piloting the materials with people outside of the supervisory team as and when they had the chance to offer feedback. Although the target population were not involved in a steering group manner, they were very much the focus of the development in each phase. The Delphi study best utilised this as it had the most involvement with people affected by cancer overall.

The methodological approach to this research had to change when the COVID-19 pandemic restrictions were introduced. The original intention for the user experience evaluation was to conduct this in person with each available member of staff at Tenovus Cancer Care and then to take it out to the service users so they could also test it out. There would have been an opportunity to do this prior to the pandemic restrictions and this definitely had the greatest impact on the final evaluation. Despite the first user experience evaluation being conducted online this still yielded substantial data and allowed for an effective evaluation. This data probably would have been strengthened with more participants in each category that had been identified prior to recruitment but there was enough generalisable data collected that it did not have a great impact on the outcome. This differs slightly when considering the final user experience study. It was felt that it would be appropriate to test the 'patient facing front' in addition to the 'admin facing front' to ensure that it achieved the desired purpose, was reliable and generally just worked effectively. This is something that could have been testing with a set of patient representatives on a steering group had his been set up effectively, however instead it was combined with piloting the psychosocial toolkit. The whole process of the final study was not an ideal set up but given the time restraints of the remainder of the PhD and the ever-changing position that Tenovus were in in regard to their

service delivery it was the best possible option. The second user experience study did not really yield significant enough results to provide any feedback to the developers, as there were only three people who completed it there was not enough follow-up data to provide a meaningful result from the UX questionnaires (UEQ and SUS). A smaller sample may have benefitted from a more qualitative approach, perhaps that which mirrored the methods and procedure of the first user experience study more, but this was not feasible at the time. The approach to the final phase of this study was about taking advantage of the resources available. The final phase of this PhD was always intended to result in a robust psychosocial evaluation of a live Tenovus service but following the pandemic this was no longer an option and did not seem that it would ever become an option again with the impact of the pandemic on charities such as Tenovus. During the later stages of 2020 and into 2021 two separate studies were developed in an attempt to replicate the robust nature of the original final study. Within this included a quantitative needs assessment of the impact of the COVID-19 pandemic on people affected by cancer in Wales using some, but not all of the toolkit measures. When that study did not recruit, a smaller, qualitative study was developed to try and further understand the experiences of people affected by cancer, living in Wales during the pandemic. Unfortunately, neither of these studies were successful in recruiting participants, however in hindsight this was a better outcome as it allowed time for the restrictions to ease and for Tenovus to start to regain some normality that allowed the T:POT interface to undergo a smaller scale pilot study. As a researcher there is nothing that could have been done differently in this scenario, it was a case of adapting to the current situation and attempting to overcome the challenges it posed.

Development and UX testing of interface

The evaluation of mobile health (mHealth) or electronic health (eHealth) applications are the closest thing to draw comparisons with for this research. mHealth and eHealth applications are usually evaluated by usage and uptake rates rather than in-depth usability or user experience evaluations. A systematic review conducted by Bunevicine et al., (2021) identified mHealth and eHealth interventions that were designed to improve quality of life in people affected by cancer and despite being evaluated against psychosocial outcomes, the actual development or design of the app/intervention was not reported or discussed. This provides difficulty when drawing conclusion on the effectiveness of a mHealth/eHealth application because the experience the user has had is not evaluated and it creates questions surrounding the regulation of these apps (Kumar et al., 2015) User experience testing has rarely been reported as an important facet of psychosocial measure development due to these usually presenting as a collection of questionnaires which are paper based or use a generic online survey tool. The approach taken in this research combined the use of a psychosocial toolkit with a bespoke interface and a thorough evaluation of both elements. By drawing from the field of applied computing combined with psychological techniques the interface employed the Think Aloud and validated user experience scales. The entire study was also conducted online which was not the intended approach, however this did work well in the end. Originally there had been a plan to utilise eye-tracking software to add an extra layer of usability data to the study. In hindsight, the eye-tracking data would not have added to the psychological understanding or contribution to this research and utilising the Think Aloud method and user experience questionnaires added much richer data than anticipated.

When participants were asked to use the Think Aloud method, they were given the option to do so, so as to ensure all participants felt comfortable taking part. It is interesting to

consider whether this study would have achieved anything different if it had been conducted in person as originally planned. The study came with some limitations, mostly surrounding participant numbers and the virtual element. As has been discussed in great detail, the pandemic hugely affected staffing numbers at Tenovus and therefore the participant pool was much smaller. On reflection this worked out well as there were enough members of staff from Tenovus who brought a different knowledge to those who did not work for Tenovus and allowed people with a range of expertise to take part. This may have added richness to the user experience data, however another phase of testing with just Tenovus staff would be interesting to conduct now that the interface has been finalised. In an ideal scenario, the final study would have been done in collaboration with the research team so everyone could see how the T:POT interface worked in practice.

Live evaluation: does T:POT work in practice

Unfortunately, one of the key limitations of the thesis was the inability to carry out a robust psychosocial evaluation of T:POT through a live evaluation of a Tenovus initiative. The original aim was to follow good practice in intervention evaluation as supported by the MRC framework (Skivington et al., 2021) and to conduct a longitudinal evaluation of a new service being offered by Tenovus which was Activate Your Life (AYL). AYL is a four-week psycho-education programme based on acceptance and commitment therapy. As detailed in Chapter One, as a consequence of funding restrictions during the COVID pandemic, Tenovus ceased all psychosocial support during the first year of the pandemic (start of the final year of this PhD) with only their telephone advice line remaining. The inevitable pause to this phase of the study meant that it was not until 18 months later that any attempt to test out T:POT was possible, and only on a limited service.

When Tenovus resumed their services, they did so under a new CEO and a new approach to navigating a post-pandemic world as a charity. For Tenovus this meant a lot of their funding for research and services was significantly reduced and they would be reducing their psychosocial support offering for the foreseeable future. The service that they were continuing to provide due was the Sing With Us community choirs.

As discussed in some detail in Chapter Seven, a plan was agreed to be able to test out the T:POT and also collect some vital data for the research and insight team. There were positives and negatives of using this approach, of course the positive was that the T:POT would be able to be tested in a participant pool of people who have used a Tenovus service and having direct access to them was a benefit. The negatives to this approach were a lack of control over where the study was advertised and how, and it then made the entire study duration very long with a lot of opting in and out at different stages. Unfortunately, the proportion of people who have never had a cancer diagnosis is far higher than that of those who have, who attend the choirs. This meant that the participant pool was already smaller and with having less control over how often and how it was advertised, this did not foster a large recruitment drive. With this in mind, the results of the study that was conducted are by no means robust enough to be considered a psychosocial evaluation, however they do demonstrate that the T:POT works, and it works within the interface. It was important to see whether the data that the T:POT collected was accurate and whether the 'live data' on the interface accurately represented the data being collected. It allowed the T:POT interface to be used in a live setting despite it not recruiting a significant number of participants, it was still a valuable process for it to undergo. The T:POT still needs to be used to conduct a larger scale evaluation in order to get more value from it. Tenovus will be able to explore individual results, look at differences between age groups, genders and even more critically, compare two

services against each other using the same key outcomes. This is the main element of the T:POT interface that remains unanswered, of whether it can accurately compare the psychosocial impact of two services against each other.

The way in which the T:POT interface was developed and evaluated means that it is very straightforward to implement, and the data collected in the user experience evaluation provides support for this. The head of the research and insight team and Tenovus will hold the details for the interface whereby they can share these with who they choose. Users can then create their own unique profiles to view and/or conduct psychosocial evaluations using the T:POT. The developers (Vindico) pledge to provide support for further developments to the interface and an agreement was made that should Tenovus wish to proceed with developing the interface further they could do with the help of Vindico. An ownership agreement was made very early into the collaboration between Vindico and Tenovus where it was agreed that Vindico would be able to use the shell of the prototype that had been developed for any other business. The data collected within the interface will only be available to users at Tenovus and is password protected. There is scope to work with Vindico to develop the same framework for other organisations and charities.

Practical recommendations for psychosocial support initiatives

The rationale behind this research started with having spent time working with Tenovus on previous projects evaluating the psychosocial impact of their services. From what has been learnt over the course of four years is that cancer continues to have a negative impact on a person's psychosocial health and services must continually adapt to suit the ever-changing needs of these individuals. However, to do this, organisations must know who their audience are, what their needs are and whether the service being provided to them is fit for

purpose. The value that came from involving people with cancer during the Delphi stage and the user experience evaluation stage meant that they had involvement from the start. Of course, as has already been discussed in earlier chapters this level of involvement can and should be much more in-depth, structured, and efficient by following good practice for patient and public involvement, such as the Macmillan Research Impact framework. What has also been learnt whilst examining the methodological quality of the PROMS that were identified in the systematic review is that authors developing these outcome measures are not all following the same process and that there are no exact criteria that have to be met in order for a scale to be validated. It is very reliant on their reliability scores once they have been piloted and already used in the target population. Using the COSMIN process highlighted all of the additional factors that should be considered when developing an outcome measure in order to ensure it is a high a quality as possible in the hope that high quality outcome measures will produce higher quality and more credible outcomes.

There are two separate things to contribute to the field within this thesis – the toolkit itself and the framework for identifying the measures and key outcomes within the toolkit. The toolkit that has been developed can be used and applied in any situation that is aiming to evaluate the psychosocial impact of an intervention and the key health outcomes identified are supported as key research priorities (Corner et al., 2007; Jarett et al., 2013; Boundouki et al., 2019). Additionally, the framework in which it was developed can be applied to any other health condition. Going through the process of conducting a systematic review and methodological quality examination, a method of patient involvement and consensus building such as the Delphi technique and then mapping those things together is a solid framework for establishing key health outcomes and choosing the appropriate measures. This lines up with everything that is discussed by authors such as Mokkink et al., (2018) and Terwee et al.,

(2010) who developed the COSMIN process, whereby they believe that outcome measures should be developed under a strict process and importantly where they involve the target audience.

Overall, those who are choosing outcome measures to accurately evaluate the psychosocial impact of an intervention should consider more than just the reliability scores reported in the most recent studies and look further into how they were developed and by what standards and should perhaps consider using a framework like the one used in this thesis, to develop a toolkit to best suit the needs of their target population.

A reflection on patient and public involvement

The following reflection will draw upon Gibbs (1998) reflective cycle to examine the level of PPI within this work.

This research attempted to follow the principles of meaningful involvement as advised by the Health Research Authority (HRA), which talks about involving enough of the right people and to describe how it will help that population. At the beginning of this PhD, a steering group was to be set up which would have included patients, public and professionals who would have ideally reviewed and been involved in the co-design of everything within this thesis from the start. Unfortunately, this is something that was unsuccessful due to a range of factors, one being a lack of structure/adherence to a model of good practice and a general lack of up take. At this time, I underestimated the importance of PPI and how something like a steering group would have been an integral part of co-design and co-production of this toolkit interface. Despite not having an official steering group, there were multiple professionals and academics outside of my supervisory team who offered their expertise on various elements of the work. Although a structured model was not followed, any opportunity to involve other

people at various stages was encouraged. During the first 18 months of the PhD (pre-pandemic), I was able to visit each of the services that Tenovus Cancer Care offer and was able to engage with people affected by cancer, find out what is important to them about the services and share what the research was aiming to do. Formal involvement from people affected by cancer came mostly via the Delphi consensus study (see chapter 5). However, as reflected earlier in this chapter, they were participants in a study. At this time, it felt it was enough to use the Delphi study as a way of including PPI into the thesis whilst also getting the data needed for the toolkit. Therefore, although the guidance suggest that individuals should not be active participants, the Delphi technique could act as a good method of PPI. Other points of involvement occurred during the user experience evaluation phases. Staff, volunteers and lay individuals took part in the UX evaluation, which again although they were acting as participants, they were contributing to the design and testing process of the toolkit and interface.

If I were to begin this process again I would incorporate a more structured model for PPI to ensure that there was as much input from the target population as possible and would also make more use of the established resources available such as Tenovus Cancer Care's Research Advisory Group (RAG). The work undertaken in this thesis represented more of Participatory Action Research approach whereby the participants of the research were part of the process of methodological enquiry. There would be an established steering group made up of key stakeholders, patients/people affected by cancer and the public. There would be clear guidance from the start about when and how they would contribute to the work being undertaken and at each phase of the research they would be given the opportunity to review and adapt the research at that stage. As well as following the guidance from organisations such as INVOLVE, the HRA and NIHR, I would follow the UK standards for public involvement.

This includes inclusive opportunities, working together, support and learning, governance, communications and impact. See Figure 34 below for a full description of these steps.

Figure 34

The UK Standards for Public Involvement

1. Inclusive opportunities: offer public involvement opportunities that are accessible and that reach people and groups according to research needs
2. Working together: work together in a way that values all contributions, and that builds and sustains mutually respectful and productive relationships
3. Support and learning: offer and promote support and learning opportunities that build confidence and skills for public involvement in research
4. Governance: Involve the public in research management, regulation, leadership and decision making
5. Communications: use plain language for well-timed and relevant communications as part of involvement plans and activities
6. Impact: seek improvement by identifying and sharing the difference that public involvement makes to research

Despite the issues identified and lessons learnt from the PPI and PAR methods within this body of work, the toolkit has been informed by the target population and reflects the good quality principles reflected when developing measure, whereby the target population are involved in measurement and outcome selection. I can be confident that with the resources available at the time, the right people were involved at the right time and the end result reflects that of the target population.

The Thesis and the COVID-19 pandemic

This thesis must acknowledge the impact of the COVID-19 pandemic on the research that was conducted and the some of the issues faced a result of the impact of the pandemic. This studentship began in 2018 and had a significant amount of empirical data collection

planned for 2020 as the final phase of the PhD progressed. The initial aim of the PhD was to use the protocol and interface that had been developed and tested through phase one and two, to conduct a psychosocial evaluation of a live service being offered by Tenovus Cancer Care. In March 2020 when the pandemic and associated lockdown restrictions were introduced, Tenovus Cancer Care halted all of their in-person services and significantly reduced their telephone support services. Tenovus, like many other organisations were forced to place staff on the available furlough schemes and reduce their outgoings as a publicly funded charity organisation. In the initial stages of 2020, adaptions were able to be made to conduct some of the research remotely. For example, in Chapter six it discussed the usability evaluation of the interface that had been developed. This had initially been planned to be conducted in person at Tenovus Head Office with a large number of staff being available to take part. Instead, this was conducted remotely, which although worked very efficiently, the participant pool was significantly reduced. By mid-2020 Tenovus had not resumed any of their psychosocial services and therefore attention turned how phase three would be feasible. Two attempts were made to change the direction of the PhD research, using the protocol that had been developed to attempt to assess the unmet needs and relative impact of the COVID-19 pandemic on individuals with cancer. Both a quantitative and qualitative approach were taken to try and achieve this, however neither of these studies recruited any participants. It is thought that this could be attributable to the already research saturated population of people affected by cancer that had now grown in size due to everyone wanted to explore the impact of the pandemic.

Therefore, phase three of this research has been adapted multiple times since the inception of the studentship to reflect the ever-changing impact of the pandemic. By the end of 2021 Tenovus Cancer Care had resumed some of their services including resuming their face-

to-face ‘Sing With Us’ choirs. By this time, the protocol and interface were ready to be implemented and therefore a pilot study was developed in order to test out the feasibility of the psychosocial evaluation protocol and the usability of the data visualisation interface as an online survey tool.

KESS studentship reflections

Due to the nature of the funding for this research there was a requirement to complete a number of placement hours with the partner organisation, which in this case was Tenovus Cancer Care. The hours completed formed a large part of information gathering for the latter stages of the research. Getting to know Tenovus’ needs and current practices was imperative to shaping the design and function of the interface to ensure it had the best chance of meeting their needs. As a reminder the KESS Studentships are designed to increase the research capacity of small to medium organisations by linking them with a research project which in turn creates a qualification for the student whilst also developing something tangible.

Throughout the three-year funded period KESS provided workshops relating to developing higher level skills as a researcher, opportunities to network with other students and professionals, three-minute thesis competitions and awards ceremonies to encourage an inclusive research environment. As part of the KESS development students were required to collect ‘credits’ for each activity per year. A number of things qualified for ‘credits’ such as attending workshops put on by KESS, attending and presenting at conferences and teaching. Most of the credits collected during this PhD were through attending and presenting at conferences and teaching related activity. As a PhD student at UWTSD I was gratefully given the opportunity to undergo paid teaching work whilst studying. One of the main events that KESS provide is the Doctoral College Residential trip, one of which is in the UK/your home

nation and one of which is international. Unfortunately, in the year that I was due to attend both residential trips they were cancelled due to the pandemic. KESS did not resume their residentials for the remainder of my candidature but offered alternative methods of collecting credits which were through workshops delivered online.

Overall recommendations

Along with the lessons learnt along the way, there are a number of recommendations that can be made from this body of work in relation to the health research landscape and cancer policies. An overview of the cancer policies from 2016-24 were presented along with the overlapping priorities between that and the PhD aims and objectives in Chapter one (Figure 2). Firstly, this body of work demonstrates that an innovative tool has been produced that incorporates the priority areas of these policies whilst addressing the psychosocial health of the cancer population. This work as a whole should help to improve psychological outcome evaluation for Tenovus Cancer Care by providing a more user friendly method of collating and comparing key patient-driven psychosocial outcome data, helping to promote a research ready environment for service providers. Secondly, and importantly, the approach adopted within the thesis can easily be adapted to develop a core set of outcome measures and outcome database for any other health condition, if the same broad methodological framework is followed.

Figure 2

Overlapping priorities between cancer policies and PhD aims & objectives

A third recommendation based on the limitations identified above is to ensure a clear PPI strategy to ensure that the people that are the subject of the research are active research partners/stakeholders from the outset. A fourth and final recommendation is the need to ensure that robust evaluation protocols are put in place alongside the use of any patient outcome database such as T:POT; this is critical to sustaining and demonstrating the long term impact of any sort of psychosocial health intervention. In the context of the third sector service provision, there is likely to be a parallel need to train key members of the organisation in how to navigate any such tool and to seek ongoing feedback around usability and acceptability to ensure it retains its validity over time.

Conclusions

The research conducted for this thesis adds a unique perspective to the field of psychosocial oncology research. Its interdisciplinary approach has demonstrated the need to ensure that appropriate frameworks for choosing and/or developing the best outcome measures to evaluate the psychosocial health of individuals affected by cancer are implemented. In contrast to much of the existing research on PROMS and PREMS, this thesis demonstrates that choosing good quality outcome measures need to be much more than just assessing reliability scores and include greater critical consideration of *how* they were actually developed, *who* they were developed *with*, and finally, who they are intended *for.* The abundance of outcome measures that exist are not conducive to creating parity across psychosocial cancer interventions and continue to create ambiguous data on the relative effectiveness of different cancer support initiatives. The T:POT can be used in any cancer population to measure the psychosocial health of that population at any time point, providing the ability to directly compare the same key outcomes across different initiatives and time points. As already stated, the interface design can be easily adapted and taken forward and used in any organisation who are interested in choosing the best quality measures for evaluating psychosocial health in a particular patient population. Critical to the sustainability of this approach however would be a stronger model of PPI throughout the process, including in any impact evaluation and dissemination activities.

The measures contained within the toolkit are designed to focus on cancer in general which was decided to create a base toolkit for Tenovus, where they could add disease specific modules in the future. The work undertaken in this thesis supports the need for a generic psychosocial cancer evaluation toolkit, especially with the everchanging landscape for Tenovus Cancer Care who continue to provide support to all people affected by cancer. The

emerging evidence from this thesis indicates that T:POT may meet this requirement, although this needs to be further evaluated in a larger evaluation study.

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Appendix

Appendix A – Ethics

Ethics form 1

APPLICATION FOR ETHICAL APPROVAL

In order for research to result in benefit and minimise risk of harm, it must be conducted ethically. A researcher may not be covered by the University's insurance if ethical approval has not been obtained prior to commencement.

The University follows the OECD Frascati manual definition of research activity: "creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications". As such this covers activities undertaken by members of staff, postgraduate research students, and both taught postgraduate and undergraduate students working on dissertations/projects.

The individual undertaking the research activity is known as the "principal researcher".

Ethical approval is not required for routine audits, performance reviews, quality assurance studies, testing within normal educational requirements, and literary or artistic criticism.

Please read the notes for guidance before completing ALL sections of the form.

This form must be completed and approved prior to undertaking any research activity. Please see Checklist for details of process for different categories of application.

SECTION A: About You (Principal Researcher)

Full Name:	Zoe Cooke				
Tick all boxes which apply:					
Member of staff:	☒	Student:	☒	Honorary research fellow:	☐

Faculty/School/Centre:	Yr Athrofa: Psychology		
Campus:	Swansea		
E-mail address:			
Contact Telephone Number:			
For students:			
Student Number:	1050478	Undergraduate	☐
Programme of Study:	PhD Psychology	Taught Postgraduate	☐
Director of Studies/Supervisor:	Dr Ceri Phelps	Research	☒

SECTION B: Approval for Research Activity

Has the research activity received approval in principle? (please check the Guidance Notes as to the appropriate approval process for different levels of research by different categories of individual)			YES	☒	NO ☐
					Date
If Yes, please indicate source of approval (and date where known):	Research Degrees Committee	☒	30/5/18		
	Faculty Research Committee	☐			
	Other (write in)	☐			

Approval in principle must be obtained from the relevant source prior to seeking ethical approval.

SECTION C: External Ethical Guidance Materials

Please list the core ethical guidance documents that have been referred to during the completion of this form (including any discipline-specific codes of research ethics, and also any specific ethical guidance relating to the proposed methodology). Please tick to confirm that your research proposal adheres to these codes and guidelines.	
British Psychological Society Code of Human Research Ethics	☒

UWTSD Research and Integrity Code of Practice	☒
General Data Protection Regulation	☒
UWTSD Data Management Policy	☒
NRES/NHS Ethical Guidance	☒

SECTION D: External Collaborative Research Activity

Does the research activity involve collaborators outside of the University?	YES	☒	NO	☐
If Yes, please provide the name of the external organisation and name and contact details for the main contact person:				
Institution	Tenovus Cancer Care			
Contact person name	Dr Tim Banks, Research Manager/Company Supervisor			
Contact person e-mail address				

Where research activity is carried out in collaboration with an external organisation

Does this organisation have its own ethics approval system?	YES	☐	NO	☒
If Yes, please attach a copy of any final approval (or interim approval) from the organisation				

SECTION E: Details of Research Activity

Indicative title:	The Psychosocial Cancer Evaluation Toolkit: Developing a tailored evaluation protocol and research outcome database for the evaluation of cancer support and prevention initiatives.		
Proposed start date:	01/10/2018	Proposed end date:	02/02/2021
Purpose of research activity (including aims and objectives) Outline the purpose, aims and objectives of the research activity, including key research questions. Show briefly how existing research has informed the proposed activity and explain what the research activity will add and how it addresses an area of importance. (Maximum 300 words)			
This application for ethical approval relates to a fully-funded KESS 2 PhD studentship which was awarded in August 2017 and approved by the UWTSD's Research Degrees Committee			

in May 2018. The PhD studentship is a collaboration with Tenovus Cancer Care (TCC) and internal supervision coming from the School of Psychology (Dr Ceri Phelps is Director of Studies) and School of Applied Computing (Dr Kemi Ademoye and Dr Nik Whitehead). The main aims of the PhD are 1) to develop a psychometrically robust evaluation protocol and toolkit that will enable Tenovus to evaluate the extent to which their various cancer support and cancer prevention initiatives improve core cancer outcomes and patient/client experience, and 2) to create a user-friendly computer interface that will enable Tenovus to use this toolkit to evaluate the relative impact and potential sustainability of psychosocial cancer support and prevention initiatives.

The need to provide robust psychosocial support to the growing number of individuals affected by cancer is well recognised (MacMillan, 2016; Shouten et al., 2016), with The Wales Cancer Network (2016) highlighting the need to improve the way in which key health outcomes amongst this population are measured and evaluated. In line with the 'Cancer Delivery Plan for Wales 2016-2020' this PhD proposes to address this issue through the following research objectives: :

To identify core evaluation outcomes that will inform the development of a Psychosocial Evaluation Toolkit for cancer support initiatives following a systematic review of the literature, stakeholder consultation and consensus building

To produce a bespoke user-friendly interface where the toolkit can be easily mapped and utilised across different initiatives, both within and beyond Tenovus.

To evaluate the potential usefulness and acceptability of this toolkit and database through a live evaluation of a current Tenovus initiative and stakeholder feedback

(this box should expand as you type)

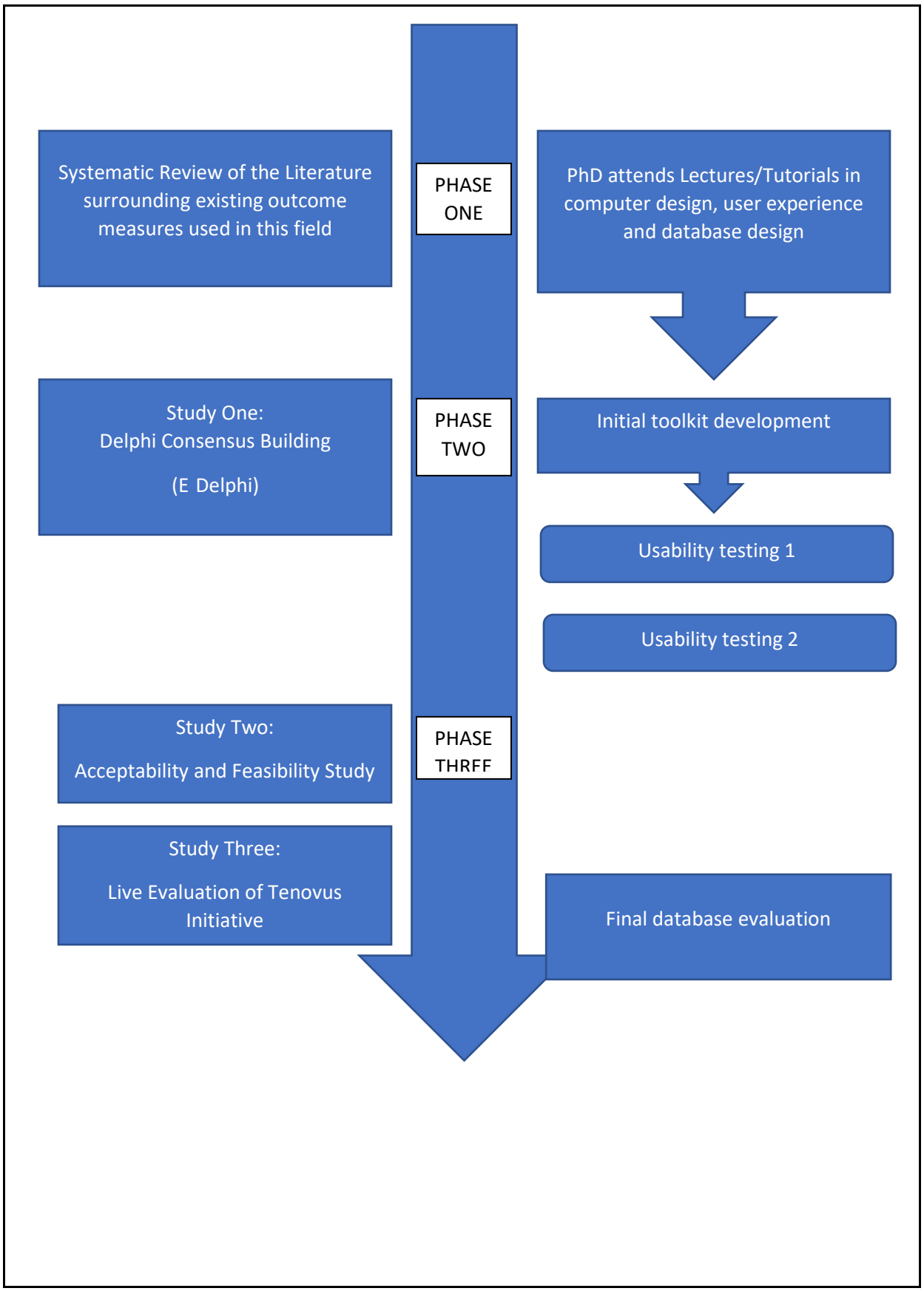
Proposed methods

Provide a brief summary of all the methods that may be used in the research activity, making it clear what specific techniques may be used. If methods other than those listed in this section are deemed appropriate later, additional ethical approval for those methods will be needed. (Maximum 600 words)

The plan of work for this PhD will involve a multi-phased mixed methods approach. Following an initial in-depth systematic review of the existing empirical literature around psychometric measurement of psychosocial interventions for cancer (Phase 1), the second phase will involve an Online Modified Delphi (OMD) approach or E-Delphi (Kodyakov et al., 2016) to engage with key stakeholders in the co-production of an identified set of outcome measures and preferred design interface. The final phase consists of two parts (Study Two and Three), Study Two will involve acceptability and feasibility testing of the toolkit and Study three will be a live evaluation of a Tenovus initiative using the toolkit.

As indicated in Figure One, the development of the computer interface will occur in parallel with the empirical work carried out. There is not an expectation that the Principle Researcher (PhD Student) will build the interface as the primary discipline of the PhD is Health Psychology, however the PhD student will have significant input into the design elements in the early stages of development through the systematic review and Delphi study (empirical study one) and with the ongoing acceptability, feasibility and pilot testing of the interface through empirical studies two and three.

Figure 1. PhD Structure


Systematic Review of the Literature surrounding existing outcome measures used in this field
PHASE ONE
PhD attends Lectures/Tutorials in computer design, user experience and database design
Study One:
Delphi Consensus Building
(E Delphi)
PHASE TWO
Initial toolkit development
Usability testing 1
Usability testing 2
Study Two:
Acceptability and Feasibility Study
PHASE THRFF
Study Three:
Live Evaluation of Tenovus Initiative
Final database evaluation

Phase One (Months One to Six): Systematic literature review: A systematic review of existing outcome measures used in cancer support and prevention initiatives leading to recommendations regarding the psychometrically strongest core outcome measures within this area. During this phase the investigator will also undergo training in basic computer programming and interface development, supported by the second academic supervisor.

Phase Two (Months Six to Twelve): Empirical Study One:E-Delphi: The Delphi consensus building technique (Dalkey & Helmer, 1963) involves a group of predefined 'experts' pooling together their knowledge to explore areas of research in order to reach a convergence opinion on a real-world subject (Baines & Regan de Bere, 2012). For this project an online modified Delphi (OMD) or e-Delphi (Khodyakov et al., 2016) will be employed using 'Qualtrics' online survey platform. Using an e-Delphi approach, key stakeholders and patient groups from the Cancer field will be recruited in order to establish and agree a core set of evaluation outcomes and design preferences for the Toolkit interface. Details regarding the identification and recruitment of stakeholders are detailed in section G and will include patient groups, Tenovus representatives, cancer specific medical professionals, psycho-oncology researchers and other representatives from healthcare and psychosocial services. By including a wide range of stakeholders, it provides diversity in the range of expertise (Jorm, 2015) leading to a more credible outcome (Iqbal & Pipon-Young, 2009).

The e-Delphi will consist of a series of questionnaire rounds to elicit feedback on the most appropriate set of psychosocial outcome measures, after each round the data will be analysed and fed back to participants until (percentage of consensus) is reached on each topic. Data will be analysed using a ranking/rating technique, following each round participants will be shown their results in relation to the overall results and given an opportunity to amend their decision which is considered an important part of moving towards consensus (Powell, 2003). Advantages for using this method include participants remain unknown to each other which is an important element for Delphi research (Iqbal & Pipon-Young, 2009) being able to reach a diverse range of people, it is cost effective and time saving as participants need not travel to take part and responses are not influenced by potential dominating group members as all feedback is anonymised.

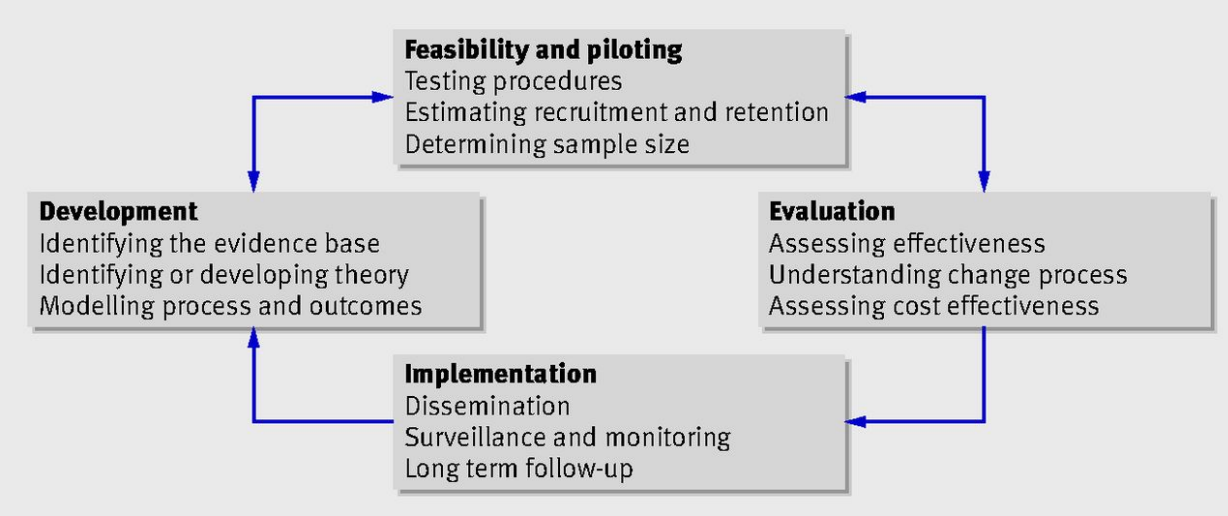
Phase Three (Months Twelve to Thirty): Empirical Study Two: Acceptability and Feasibility Pilot Test

Piloting and evaluation of the Psychosocial Cancer Evaluation Toolkit and interface. Following good practice principles of intervention development and evaluation (MRC, 2001), the toolkit and database will undergo rigorous pilot testing for ease of use and acceptability, accuracy of data comparison and analysis, and cost-effectiveness (study two). It will involve asking willing staff at Tenovus to engage with the interface in ways appropriate to their specific roles and then to report back using both qualitative (focus group) and quantitative outcomes (process measures capturing the following outcomes: ease of use (learning the system, navigation), time intensity, frequency of use, perception of value and cost-effectiveness. It may also involve the use of eye tracking software to help evaluate the user experience of the toolkit, allowing

patterns to show where users spend the most time within the toolkit, any difficulties they may have when navigating it and the overall satisfaction of the interface.

Empirical study Three: The final study will then involve a systematic psychosocial evaluation of a current initiative within Tenovus using the toolkit and database (Study Three). This will represent an exploratory trial following the MRC framework, with outcome measures assessing not only the effectiveness of the intervention for a specific cancer population but, importantly, the effectiveness of the toolkit/interface in assisting with a systematic evaluation. As the precise intervention, target population and outcome measured cannot be identified until completion of phases one and two, this final study will be resubmitted for University Ethics Approval at an appropriate stage and will also be submitted for NHS ethics approval (both the PhD student and Director of Studies have previous experience of successfully obtaining NHS ethics approval for psychosocial intervention studies in the cancer field).

In the final six months of the project, alongside the thesis write-up, final revisions will be made to the toolkit and training offered to all Tenovus staff and key identified stakeholders alongside the provision of a detailed user manual.



(this box should expand as you type)

Location of research activity

Identify all locations where research activity will take place.

The location of the research activity is dependent on the phase of study as detailed below.

Phase One: Systematic literature review will be conducted electronically and does not involve participant contact

Phase Two: Study One –E-Delphi study the Delphi consensus building technique will be conducted using an online platform such as Qualtrics to target a wide range of viewpoints across Wales/UK and ensure anonymity amongst participants.

Phase Three

Study Two – the acceptability and feasibility of the toolkit for those working at Tenovus in various roles will be explored through this study conducted at Tenovus Headquarters in Cardiff, South Wales

Study Three – The location of the research activity for study three will be confirmed through the subsequent ethical approval form, but as this will target individuals affected by cancer this study will also apply for NHS ethics approval.

(this box should expand as you type)

Research activity outside of the UK

If research activity will take place overseas, you are responsible for ensuring that local ethical considerations are complied with and that the relevant permissions are sought. Specify any local guidelines (e.g. from local professional associations/learned societies/universities) that exist and whether these involve any ethical stipulations beyond those usual in the UK (provide details of any licenses or permissions required). Also specify whether there are any specific ethical issues raised by the local context in which the research activity is taking place, for example, particular cultural sensitivities or vulnerabilities of participants.

N/A

(this box should expand as you type)

SECTION F: Scope of Research Activity

Will the research activity include:	YES	NO
Use of a questionnaire or similar research instrument?	☒	☐
Use of interviews?	☒	☐
Use of diaries?	☐	☒
Participant observation with their knowledge?	☐	☒
Participant observation without their knowledge?	☐	☒
Use of video or audio recording?	☒	☐
Access to personal or confidential information without the participants' specific consent?	☐	☒
Administration of any questions, test stimuli, presentation that may be experienced as physically, mentally or emotionally harmful / offensive?	☒	☐
Performance of any acts which may cause embarrassment or affect self-esteem?	☐	☒
Investigation of participants involved in illegal activities?	☐	☒
Use of procedures that involve deception?	☐	☒
Administration of any substance, agent or placebo?	☐	☒
Working with live vertebrate animals?	☐	☒
Other primary data collection methods, please explain in this box Delphi consensus building technique (Dalkey & Helmer, 1963) involves a group of predefined 'experts' pooling together their knowledge to explore areas of research in order to reach a convergence opinion on a real-world subject (Baines & Regan de Bere, 2012). For this project an online modified Delphi (OMD) or e-Delphi (Khodyakov et al., 2016) will be employed using 'Qualtrics' online survey platform.	☒	☐

If NO to every question, then the research activity is (ethically) low risk and may be exempt from some of the following sections (please refer to Guidance Notes).

If YES to any question, then no research activity should be undertaken until full ethical approval has been obtained.

SECTION G: Intended Participants

Who are the intended participants:	YES	NO
Students or staff at the University?	☐	☒
Adults (over the age of 18 and competent to give consent)?	☒	☐
Vulnerable adults?	☒	☐
Children under 18?	☐	☒
Prisoners?	☐	☒
Young offenders?	☐	☒
Those who could be considered to have a particularly dependent relationship with the investigator or a gatekeeper?	☐	☒
People engaged in illegal activities?	☐	☒
Others (please identify):	☐	☐

Participant numbers and source Provide an estimate of the expected number of participants. How will you identify participants and how will they be recruited?
Phase One: No participants required Phase Two: Study One – participants for this study will consist of pre-defined 'experts' within the cancer field. Turoff (2002) recommends a panel size of 10 to 50 for an effective e-Delphi study. This includes those who have experience with cancer themselves or in their families, and professionals such as oncologists and cancer nurse specialists. For this study, individuals with experience of cancer will be recruited through Tenovus Cancer Care research network and other cancer charities/networks in Wales, with an initial target sample of 50 to ensure a range of skillsets and experiences. This is an established network of individuals who have expressed interest in taking part in research and have consented to being contact in the event of such opportunities. The network currently holds a database of up to 1000 individuals who have given consent to be contacted about research opportunities. Contact will be made with other cancer charities within Wales, the Welsh Cancer Alliance, Wales Cancer Network, the British Psychosocial Oncology Society and the National Cancer Research Institute (NCRI) to request cooperation in disseminating information about the study. Phase Three: Study 2 – The purpose of this study is to test the acceptability and feasibility of the database, this will happen in two stages. Throughout stage one the database will undergo usability testing during its development, initially by students from the School of Applied Computing in relation to the technical aspects, and secondly; stage two will target staff from Tenovus Cancer Care who will be

recruited via the Research Team within Tenovus who send out a quarterly newsletter with details about upcoming research opportunities.

Study 3 – The final study will represent an exploratory trial following the Medical Research Council framework (MRC, 2000) using the toolkit database to evaluate a live Tenovus initiative. As the precise intervention, target population and outcome measures cannot be identified until completion of phases one and two, this final study will be resubmitted for University Ethics Approval at an appropriate stage and will also be submitted for NHS ethics approval (both the PhD student and Director of Studies have previous experience of successfully obtaining NHS ethics approval for psychosocial intervention studies in the cancer field). It is expected that this study will involve participants who have experienced cancer and are directly engaging with a service provided by Tenovus Cancer Care as we will be seeking to collect psychosocial data from service users accessing an agreed Tenovus Initiative.

this box should expand as you type)

Information for participants:	YES	NO	N/A
Will you describe the main research procedures to participants in advance, so that they are informed about what to expect?	☒	☐	☐
Will you tell participants that their participation is voluntary?	☒	☐	☐
Will you obtain written consent for participation?	☒	☐	☐
Will you explain to participants that refusal to participate in the research will not affect their treatment or education (if relevant)?	☒	☐	☐
If the research is observational, will you ask participants for their consent to being observed?	☐	☐	☒
Will you tell participants that they may withdraw from the research at any time and for any reason?	☒	☐	☐
With questionnaires, will you give participants the option of omitting questions they do not want to answer?	☒	☐	☐
Will you tell participants that their data will be treated with full confidentiality and that, if published, it will not be identifiable as theirs?	☒	☐	☐
Will you debrief participants at the end of their participation, in a way appropriate to the type of research undertaken?	☒	☐	☐
If NO to any of above questions, please give an explanation			
(this box should expand as you type)			

Information for participants:	YES	NO	N/A
Will participants be paid?	☐	☒	☐
Is specialist electrical or other equipment to be used with participants?	☒	☐	☐
Are there any financial or other interests to the investigator or University arising from this study?	☐	☒	☐
Will the research activity involve deliberately misleading participants in any way, or the partial or full concealment of the specific study aims?	☐	☒	☐
If YES to any question, please provide full details			
Eye- tracking software may be used to aid the usability testing of the database, participants will not require any specialist training or undergo invasive instruction (Groen & Noyes, 2010). (this box should expand as you type)			

SECTION H: Anticipated Risks

Outline any anticipated risks that may adversely affect any of the participants, the researchers and/or the University, and the steps that will be taken to address them. If you have completed a full risk assessment (for example as required by a laboratory, or external research collaborator) you may append that to this form.
Full risk assessment completed and appended? Yes ☐ No ☒
Risks to participants For example: emotional distress, financial disclosure, physical harm, transfer of personal data, sensitive organisational information
All planned study procedures have been considered in relation to the British Psychological Society's Code of Human Research Ethics (2010) and relevant guidance materials from the NHS Health Research Authority. The project's focus is on the subject of Cancer and at times will invite participants who have experienced the impact of cancer either directly or indirectly. There is a potential for emotional distress however there will be protocols in place to minimise anyone taking part who may already be in high distress or as a result of the study. Participants will not be asked to disclose any financial

information and are not at risk of any physical harm whilst taking part in the study. Finally, any personal data collected will be handled in line with the GDPR (2016) and UWTSD data management policy as detailed in section J.

(this box should expand as you type)

If research activity may include sensitive, embarrassing or upsetting topics (e.g. sexual activity, drug use) or issues likely to disclose information requiring further action (e.g. criminal activity), give details of the procedures to deal with these issues, including any support/advice (e.g. helpline numbers) to be offered to participants. Note that where applicable, consent procedures should make it clear that if something potentially or actually illegal is discovered in the course of a project, it may need to be disclosed to the proper authorities

Given the focus of the research it is inevitable that at times this research will involve people who have experienced cancer directly or indirectly and who work with cancer populations. The protocols listed below are appropriate to deal with sensitive topics within a vulnerable population.

Selection of appropriate measures at each stage of empirical research- consideration given to the wording used in recruitment materials and data collection, choice of measures selected, training of student to ensure awareness of the potential to raise distress

Informed consent and right to withdraw: Participants will be given a study information sheet to detail which study they are interested in taking part in, they will be provided with a consent form (Phase Two: Study one will be conducted online therefore online consent will be obtained) and participants will be reminded that they are able to withdraw from the study at any point and their data will not be used.

Debrief: at the end of each study participants will be provided with a full debrief of the study and given details of Tenovus Cancer Care Support Line which is open to everyone and can be accessed from 8am-8pm seven days a week if there is any need for additional support.

Exclusion of people, where known to Tenovus, with high levels of psychological distress or existing mental health problems, or who are too clinically unwell to take part in this study (explained to participants in the study information sheet).

(this box should expand as you type)

Risks to investigator

For example: personal safety, physical harm, emotional distress, risk of accusation of harm/impropriety, conflict of interest

The planned empirical studies involve limited direct individual personal contact with potentially vulnerable participants, and therefore minimal risk to the researcher is expected. However, the researcher has experience of working with vulnerable adults in mental health and social care settings and has undergone several training courses such as; mental health awareness, dementia and first aid. The researcher also has a full DBS as part of being a PhD student at UWTSD.

Specifically in relation to this project, the principal researcher (PhD Student) has undergone an induction process at Tenovus Cancer Care and has previous experience of conducting research with a vulnerable population including those with cancer.

Should any distress occur as a consequence of engaging with individuals who could potentially be distressed or upset, a weekly meeting with the Director of Studies during the data collection phase of each study will enable the PhD student to debrief with the Director of Studies who has significant experience of researching cancer populations. Any unexpected adverse effect on the student will be brought to the steering group (see below) for a decision on how best to proceed.

(this box should expand as you type)

University/institutional risks

For example: adverse publicity, financial loss, data protection

In order to minimise any potential institutional risks, the proposed research will adhere to University Research Ethics & Integrity Code of Practice and at all times. Both the PhD student and Director of Studies have previous experience of researching vulnerable populations. The principles of NHS research ethics and governance will be applied at all stages of the research to ensure ultimate protection from any potential institutional harm. The director of studies is a HCPC registered Health Psychologist with over fifteen years' experience of leading psychosocial intervention studies with cancer populations. A PhD project steering group will be convened, including independent external experts, who will oversee the study processes and who will act as the first port of call in the event of any unexpected adverse circumstances occurring.

No risks are predicted to occur to the university due to all research following ethical requirements and good research practice at all times. The UWTSD data protection policy will also be followed throughout ensuring data protection is upheld. Therefore, any risks are unlikely but will be

monitored closely throughout the PhD and reported immediately to the Director of Studies in the first instance and PhD Steering Group where considered appropriate. (this box should expand as you type)
Adverse outcomes List measures put in place to limit any adverse effects or outcomes of research activity where appropriate. Include any emergency protocols.
In this instance, the research activity will be suspended and Section 11 of the UWTSD Research Ethics & Integrity Code of Practice will be followed which states - *"In all cases any adverse events occurring during the conduct of research projects must be reported to the Ethics Committee. In such cases the researcher, whether staff or student, shall withdraw from the research process with immediate effect until notified by the Ethics Committee that the University is satisfied that the research design has been modified in such a way as to mitigate further harm."*

Disclosure and Barring Service			
If the research activity involves children or vulnerable adults, a Disclosure and Barring Service (DBS) certificate must be obtained before any contact with such participants.	YES	NO	N/A
Has a DBS certificate been obtained?	☒	☐	☐

SECTION I: Feedback, Consent and Confidentiality

Feedback
What feedback will be provided to participants, how will this be done and when?

Phase Two: Study one – the process of conducting an e-Delphi study involves the use of regular feedback to participants. As detailed in section E, the e-Delphi will involve a series of questionnaire rounds given to panel members. Members are asked to rate/complete each questionnaire, the researcher will then analyse each 'round' of answers and then provide feedback to participants. This feedback will consist of the overall percentage of consensus for each item within the questionnaire and offers participants an opportunity to change/adapt their answers based on this feedback. At all times, the feedback presented is representative of all panel members and participants will not receive feedback about individual participants.

General feedback protocol which will be adhered to from Phase One to Three of the project includes:

Debrief: A full debrief will be given to participants following each phase of the project where there is participant involvement. This form with contain details of how to contact the researcher further if they wish to do so. There will also be details on there to contact the main supervisor and also contact details for Tenovus Cancer Care Support Line should they need any additional emotional support and/or guidance. Participants will be given the opportunity to receive a summary of the key findings within the study that they have taken part in at the end if they wish.

Consent: During the consent process participants will be asked whether they wish to receive a summary of the research findings which will be sent following submission of the written thesis.

(this box should expand as you type)

Informed consent

Describe the arrangements to inform potential participants, before providing consent, of what is involved in participating. Describe the arrangements for participants to provide full consent before data collection begins. If gaining consent in this way is inappropriate, explain how consent will be obtained and recorded.

The following informed consent protocol is informed by the BPS Research Ethics and Section 19.3 UWTSD Research Ethics & Integrity Code of Practice and will be followed at all times:

Study information: Potential participants will be provided with full details of the study they are interested in taking part in through the provision of an NHS-style "participant information sheet". There is no need to withhold any information about the project to participants and it will be made clear about the topics that will be explored, specifically cancer and that they may be asked about their own experiences at some point. This information will be freely available to anyone who

expresses an interest and it will be a requirement for this document to be read thoroughly prior to completing a consent form.

Consent: Participants who have read and understood the study information and would like to be involved in the study will be asked to complete a consent form. This will explicitly state what data will be collected on them, how it will be stored and who it will be shared with. Referencing the appropriate legislations as detailed in other sections of this form (GDPR, Research and Integrity Code of Practice). For Phase Two, study one will be conducted online therefore all of this information will be delivered online and they will be asked to give consent electronically. For study two participants will be taking part in person and will therefore be provided with all study materials relating to information and consent, and will be stored following the appropriate data storage procedures detailed in section J.

At no point will participants be coerced into taking part in any phase of the project, and they will be reminded throughout that they their participation is entirely voluntary, and they are able to withdraw at any point.

(this box should expand as you type)

Confidentiality / Anonymity

Set out how anonymity of participants and confidentiality will be ensured in any outputs. If anonymity is not being offered, explain why this is the case.

Section 19.6 UWTSD Research Ethics and Integrity Code of Practice guidelines and the British Psychological Society Research Ethics Guidelines will be followed at all times throughout the project.

Phase Two: Study One: the nature of the e-Delphi study requires participants identities to remain anonymous amongst other panel members to ensure that responses are not influenced by knowing who the other members of the panel are. It will also be made clear that their responses to each ‘round’ of questionnaires will remain anonymous and will be analysed before feeding information back to panel members (As detailed in Section I: Feedback).

The general protocol which will be adhered to throughout the project is as follows:

Identity of participants will only be known to the researcher and lead supervisor, any data collected from them will be anonymised within 48 hours and will be unidentifiable from analysed and published data.

Great care will be taken in deciding what sensitive data is collected and thus will be treated with the utmost confidentiality, participants will be fully aware of what data will be held on them and who has access to it. This is detailed further in Section J.

For the purposes of analysis, names, locations and other identifiable information will be omitted

For some parts of the study (study one and three) participants will be assigned a unique ID number when data is processed, and this will be used for the purposes of data analysis and allows the researcher to withdraw participant data if they request it. Where participants are not assigned an ID number, their names will be omitted from any data analysis and write up.

(this box should expand as you type)

SECTION J: Data Protection and Storage

In completing this section refer to the University's Research Data Management Policy and the extensive resources on the University's Research Data Management web pages (http://uwtsd.ac.uk/library/research-data-management/).

	YES	NO
Does the research activity involve personal data (as defined by the Data Protection Act)? *"personal data" means data which relate to a living individual who can be identified—* *(a) from those data, or* *(b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual.*	☒	☐
If YES, provide a description of the data and explain why this data needs to be collected:		
Participants names will be obtained during the consent process to ensure informed consent is obtained. Any hard copy consent forms will be stored in a locked cabinet with only the principle researcher and main supervisor having access. Electronic consent forms will be encrypted, and password protected with the principle researcher and main supervisor having access. (this box should expand as you type)		
Does it involve sensitive personal data (as defined by the Data Protection Act)? ***"Sensitive personal data"*** *means personal data consisting of information as to –* *(a) the racial or ethnic origin of the data subject,* *(b) his political opinions,* *(c) his religious beliefs or other beliefs of a similar nature,*	☒	☐

(d) whether he is a member of a trade union (within the meaning of the Trade Union and Labour Relations (Consolidation) Act 1992), *(e) his physical or mental health or condition,* *(f) his sexual life,* *(g) the commission or alleged commission by him of any offence, or* *(h) any proceedings for any offence committed or alleged to have been committed by him, the disposal of such proceedings or the sentence of any court in such proceedings.*		
If YES, provide a description of the data and explain why this data needs to be collected:		
Due to the nature of the project at times participants may be asked what their experience is of a cancer diagnosis. This information is to help inform the development of the toolkit by ensuring there is adequate representation of individuals who have experienced a cancer diagnosis. This information will be completely anonymised for the purpose of analysis and publication. (this box should expand as you type)		

Will the research activity involve storing personal data on one of the following:	YES	NO
Manual files (i.e. in paper form)?	☒	☐
University computers?	☒	☐
Private company computers?	☐	☒
Home or other personal computers?	☐	☒
Laptop computers/ CDs/ Portable disk-drives/ memory sticks?	☒	☐
“Cloud” storage or websites?	☐	☒
Other – specify:	☐	☒
For all stored data, explain the measures in place to ensure data confidentiality, including details of password protection, encryption and anonymisation:		
The confidentiality of personal data in line with GDPR (2016) and UWTSD Research Data Management Policy will be assured by: Any hard copy files such as consent forms will be stored in a locked drawer and will only be linked to the data by a unique ID code for the purposes of participant withdrawal. Data collected in Phase Two: Study One will be done so using Qualtrics online survey platform where data will be anonymised upon download. Phase Three: Study Three -Only anonymised data will be entered into the statistical package SPSS which will be password protected, however as previously stated, additional NHS ethics will be sought prior to this stage of the project. Only the PhD student and project supervisor will have access to raw data before it is anonymised Any hard copy personal data will be stored in a locked cabinet and kept separate from the main data. Only the PhD Student and main supervisor will have access. Any data stored on University owned computers will be encrypted and only the researcher and director of studies will have access. (this box should expand as you type)		

Will the research activity involve any of the following activities:	YES	NO
Electronic transfer of data in any form?	☒	☐
Sharing of data with others at the University?	☒	☐
Sharing of data with other organisations?	☒	☐
Export of data outside the European Union or importing of data from outside the UK?	☐	☒
Use of personal addresses, postcodes, faxes, emails or telephone numbers?	☒	☐
Publication of data that might allow identification of individuals?	☐	☒
Use of data management system?	☒	☐
Data archiving?	☐	☒

If YES to any question, please provide full details, explaining how this will be conducted in accordance with the Data Protection Act (and/or any international equivalent):

Data will be collected, handled and appropriately stored in accordance with The General Data Protection Regulation (GDPR, 2016), UWTSD Group Data Protection Policy and Research Data Management Policy.

In accordance with the above guidance and following the previous section which details specific steps for each phase of the study. Participants will be fully informed on the data being collected about them, how it will be stored and for what length of time and details as to how they can withdraw/access this data will be contained within the study information sheet, consent form and study debrief.

Storage: Data will be anonymised within 48 hours and any hard copy data will be stored in a locked cabinet, electronic data will be stored in a password protected file on a university computer which is also password protected.

Data sharing: only anonymised data will be used for the purposes of analysis and publication with no way of identifying individual participants. Only the PhD Student and lead supervisor will have access to the raw data.

(this box should expand as you type)

List all who will have access to the data generated by the research activity:

The PI – Zoe Cooke
Supervisory Team – Dr Ceri Phelps, Dr Kemi Ademoye, Dr Nik Whitehead

(this box should expand as you type)

List who will have control of, and act as custodian(s) for, data generated by the research activity:

Zoe Cooke and Dr Ceri Phelps

(this box should expand as you type)

Give details of data storage arrangements, including where data will be stored, how long for, and in what form. Will data be archived – if so how and if not why not.

Data will be collected and appropriately stored in accordance with The General Data Protection Regulation (GDPR, 2016), UWTSD Group Data Protection Policy and Research Data Management Policy.

Article 5 of GDPR states that data must be '*kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes subject to implementation of the appropriate technical and organisational measures required by the GDPR in order to safeguard the rights and freedoms of individuals…*
…processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures.'

Section 4 of the Research Data Management Policy will be followed at all times. Specifically Section 4.3 stating that all data collected must be:
Accurate and reliable
Identifiable, retrievable and accessible
Retained in a safe and secure manner and compliant with legal requirements
Additionally Section 4.14 details appropriate data storage and retainment as informed by the RCUK Guidance on best practice in the management of research data' the Research Councils expect that findings should still be accessible for at least 10 years after publication.

To summarise:

Storage: Data will be anonymised within 48 hours and any hard copy data will be stored in a locked cabinet, electronic data will be stored in a password protected file on a university computer which is also password protected.

Data sharing: only anonymised data will be used for the purposes of analysis and publication with no way of identifying individual participants. Only the PhD Student and lead supervisor will have access to the raw data.

SECTION K: Declaration

The information which I have provided is correct and complete to the best of my knowledge. I have attempted to identify any risks and issues related to the research activity and acknowledge my obligations and the rights of the participants. In submitting this application I hereby confirm that I undertake to ensure that the above named research activity will meet the University's Research Ethics and Integrity Code of Practice	
Signature of applicant:	Date: 27.07.2018

For students:

Director of Studies/Supervisor:	Dr. Ceri Phelps
Signature:	
Date:	27.07.2018

For staff:

Head of School/Assistant Dean:	
Signature:	
Date:	

Checklist: Please complete the checklist below to ensure that you have completed the form according to the guidelines and attached any required documentation:

☒	I have read the guidance notes supplied before completing the form.
☒	I have completed ALL RELEVANT sections of the form in full.
☒	I confirm that the research activity has received approval in principle
☐	I have attached a copy of final/interim approval from external organisation (where appropriate)
☐	I have attached a full risk assessment (and have NOT completed Section H of this form) (where appropriate)
☒	I understand that it is my responsibility to ensure that the above named research activity will meet the University's Research Ethics and Integrity Code of Practice.
☒	I understand that before commencing data collection all documents aimed at respondents (including information sheets, consent forms, questionnaires, interview schedules etc.) must be confirmed by the DoS/Supervisor, module tutor or Head of School.

RESEARCH STUDENTS AND STAFF ONLY

All communications relating to this application during its processing must be in writing and emailed to pgresearch@uwtsd.ac.uk , with the title 'Ethical Approval' followed by your name.

You will be informed of the outcome of your claim by email; therefore **it is important that you check your University and personal email accounts regularly**.

STUDENTS ON UNDERGRADUATE OR TAUGHT MASTERS PROGRAMMES should submit this form (and receive the outcome) via systems explained to you by the supervisor/module leader.

This form is available electronically from the Academic Office web pages: http://www.uwtsd.ac.uk/academic-office/

Application Process

All staff research projects and all research students must submit the Ethical Approval Form to the University Ethics Committee via the Academic Office (pgresearch@uwtsd.ac.uk). Staff

research directly in relation to personal study for taught undergraduate or Masters programmes should be submitted via the Faculty procedures explained below.

Taught masters and taught undergraduate research Ethical Approval Forms are considered within Faculties. Faculties will provide details of the specific processes for this. Where the Ethical issues within any single ethical application are of particular concern the Faculty will refer these to the University Ethics Committee. Any student activity that involves the collection of primary data needs to undergo Ethical approval, this includes assignment work as well as dissertations.

Notes for guidance in completion of this form

Section A: About You

Please complete all relevant sections

Section B: Approval for research activity

Research proposals must be approved in principle before applying for Ethical Approval. The proposal approval only becomes final when the ethical approval is received.

The process for proposal approval varies according the individual and programme of study:

Research students, by application on form PG1 to the Research Degrees Committee

Taught students by review of research proposal within Faculties (Faculties provide specific details of these processes)

Staff, by agreement by the Head of School/Assistant Dean

Section C: External Ethical Guidance materials

Many discipline areas are required to operate with the discipline specific codes of research ethics (for example health, psychology, education etc.), any such codes must be listed and you must tick to confirm that you have consulted with these.

Section D: External Collaborative Research Activity

Provide details of the external collaborative partners, where appropriate you might want to submit a copy of the external collaboration agreement with the Ethical Approval Form. If the partner requires the research to be subject to its own internal Ethical approval process then please provide details of that process and a copy of any final (or interim) approvals received from the organisation.

Section E: Details of Research Activity

Remember that the individuals reviewing this Ethical Approval Form may not have seen your research proposal, and also may not be experts in the specific area of your research. The information provided should therefore be jargon free and clearly stated.

Indicative Title: please use the same title as used on the research proposal.

Purpose: the Ethical approval process will want to ensure that the methods you propose are adequate and appropriate to address the research aims and objectives. Excessive additional data collection can be seen as unethical.

Proposed Methods: the Ethical approval process seeks to ensure that you understand the methods that are intended, and that the implementation of those methods will be appropriate and without unnecessary impact on respondents. Please be specific.

Location: this needs to mention geographical location and also local situation (for example, within Local Authority Offices in Cardiff, using a private room but close to other individuals). If you are collecting data within an organisational setting then you need to explain the permissions that you have obtained to do this.

Research Activity outside of the UK: please complete this section in detail, and note any guidance you have received. Also describe your own familiarity (or not) with the location that you will be utilising.

Section F: Scope of Research Activity

Please tick ALL of the research activities that might be undertaken. If any additional types of activity are intended then please add an extra box and describe these.

If you have answered no to all questions in F then sections G and J do not need to be completed. Section H should be considered, and may be completed. Signatures are still required in section K.

Section G: Intended Participants

Please tick all categories that might apply.

Numbers & Source: if you are using a series of different methods or research activities please list numbers for each stage/phase. Be clear about how you will find respondents. Will you use intermediaries, and if so how? How will you ensure compliance with your sampling strategy?

Information for participants: all participants should be appropriately informed about the research, what is expected of them and what will happen to the information that they provide. The Ethical review process does not ask to see this documentation, but requires this to be reviewed and approved by the Director of Studies in the case of research students, the supervisor/module tutor in relation to students on taught programmes and the Head of School/Assistant Dean in relation to staff research.

Section H: Anticipate Risks

All research carries some level of risk. The answers you provide to questions in this section will be reviewed to ensure that you have an appropriate understanding of the type of risks involved and how you can mitigate against these risks. If you have completed a full risk assessment, as required for example for laboratory work, field work, clinical tests, diving operations, or by a collaborative partner, you may append that to this form. In that case, please tick the box indicating this has been provided. You will not then be required to complete Section H.

Risk to participants Think very carefully about how your actions/questions/discussions might affect the people you are involving as participants. You might identify the risk as small but it would still be a risk. Many types of question have the potential to make respondents less content with their life / job; you need to recognise and try to ameliorate any such effects

If these are business owners, time with you may reduce profit.

In some locations physical risk is very real to both participants and yourself, please consider this.

Risk to you, the researcher Think about where you will meet people, if there are any dangers involved in the location. If you are meeting people as individuals think about using a public place. In general do not visit people in their own homes or remote locations. If you are talking to individuals about certain issues think about how their responses might affect you emotionally. What about the risk of collecting insufficient data?

Risk to the University When undertaking your research, you are acting as a member of the University (student or staff). Professionalism is important, so it is important to be well organised and well prepared. Punctuality, clarity etc. are all part of this. What will you do to ensure this? You must ensure you do not harm the good name of the University in any way and do nothing to undermine the reputation of the research it conducts and sponsors. Upholding high standards of conduct and integrity are vital in this regard. You must also conduct the research in such a way to minimise the potential for claims of negligence made against the University, its researchers and any collaborating individual or organisation. In this respect you should always comply with ethical, legal and professional frameworks, obligations and standards as required by statutory and regulatory authorities, as well as the university's Research Integrity and Ethics Code of Practice. Research misconduct in this respect can take many forms, including:

fabrication: making up results or other outputs (eg, artefacts) and presenting them as if they were real

falsification: manipulating research processes or changing or omitting data without good cause

plagiarism: using other people's material without giving proper credit

failure to meet ethical, legal and professional obligations: for example failure to declare competing interests; misrepresentation of involvement or authorship; misrepresentation of interests; breach of confidentiality; lack of informed consent; misuse of personal data; and abuse of research subjects or material

improper dealing with allegations of misconduct: failing to address possible infringements such as attempts to cover up misconduct and reprisals against whistle-blowers

Adverse Outcomes. Think carefully about the possibilities, and cover here

Section I: Feedback, Consent and Confidentiality

Feedback to participants: outline your approach. Will interview transcripts be shared with respondents to check accuracy? Will summaries of questionnaire analysis be made available to respondents in some way? Will an overview report be provided? How and when?

Informed consent: Draft letter / e-mail / or heading (or footer) section of questionnaire must be approved by DoS/supervisor (if research student), supervisor/module tutor if taught student, or Head of School / Assistant Dean if a member of staff.

Confidentiality/Anonymity. Explain clearly how you will ensure confidentiality and anonymity.

Section J: Data Protection and Storage

Before completing this section it is necessary to read the University's Research Data Management information. The questions that follow are designed to ensure compliance with the Data Protection Act as well as established research protocols.

Many research activities will involve electronic transfer of data and use of data management systems in the summarisation and analysis of data. You will need to explain these in relation to compliance with the Data Protection Act.

Think carefully about who will have access to your data, this will include supervisors and examiners. Also that a thesis will be made available via the University library and the British Library system. If you are seeking an access bar for a period of time after completion then mention it here. If you will provide a copy of your findings, or intend to give a presentation, to a facilitating/ supporting/accessing organisation then explain that in this section. But also think about the general principle of data sharing, as explained in the Research Data Management information.

In terms of storage of data please ensure security, and also mitigate against loss of data.

Section K: Declaration

Ensure the appropriate countersignatures have been provided

Look carefully at the checklist and ensure that you comply with and tick all that are relevant to your research.

APPLICATION FOR ETHICAL APPROVAL

In order for research to result in benefit and minimise risk of harm, it must be conducted ethically. A researcher may not be covered by the University's insurance if ethical approval has not been obtained prior to commencement.

The University follows the OECD Frascati manual definition of research activity: "creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications". As such this covers activities undertaken by members of staff, postgraduate research students, and both taught postgraduate and undergraduate students working on dissertations/projects.

The individual undertaking the research activity is known as the "principal researcher".

Ethical approval is not required for routine audits, performance reviews, quality assurance studies, testing within normal educational requirements, and literary or artistic criticism.

Please read the notes for guidance before completing ALL sections of the form.

This form must be completed and approved prior to undertaking any research activity. Please see Checklist for details of process for different categories of application.

Delete the Guidance Notes at the end of the form BEFORE submitting your application

SECTION A: About You (Principal Researcher)

Full Name:	Zoe Cooke

Tick all boxes which apply:		Member of staff:	☐	Honorary research fellow:	☐
Undergraduate Student	☐	Taught Postgraduate Student	☐	Postgraduate Research Student	☒

Institute/Academic Discipline/Centre:	Yr Athrofa: Psychology and Counselling
Campus:	Swansea/Distance
E-mail address:	zcooke.115632@student.uwtsd.ac.uk / zoe.cooke@uwtsd.ac.uk
Contact Telephone Number:	
For students:	
Student Number:	1050478
Programme of Study:	PhD Psychology
Director of Studies/Supervisor:	Dr Ceri Phelps

SECTION B: Approval for Research Activity

Has the research activity received approval in principle? (please check the Guidance Notes as to the appropriate approval process for different levels of research by different categories of individual)		YES	☒	NO	☐
				Date	
If Yes, please indicate source of approval (and date where known): *Approval in principle must be obtained from the relevant source prior to seeking ethical approval*	Research Degrees Committee		☒	30/05/18	
	Institute Research Committee		☐		
	Other (write in)		☐		

SECTION C: Internal and External Ethical Guidance Materials

Please list the core ethical guidance documents that have been referred to during the completion of this form (including any discipline-specific codes of research ethics, and also any specific ethical

guidance relating to the proposed methodology). Please tick to confirm that your research proposal adheres to these codes and guidelines.	
UWTSD Research Ethics & Integrity Code of Practice	☒
UWTSD Research Data Management Policy	☒
BPS Code of Human Research Ethics (2014)	☒
BPS Code of Ethics and Conduct	☒
BPS Ethics Guidelines for Internet-Mediated Research (2017)	☒

SECTION D: External Collaborative Research Activity

Does the research activity involve collaborators outside of the University?		YES	☒	NO	☐
If Yes, please provide the name of the external organisation and name and contact details for the main contact person and confirmation this person has consented to their personal data being shared.as part of this collaboration.					
Institution	Tenovus Cancer Care				
Contact person name	Dr Tim Banks, Head of Research/Company Supervisor				
Contact person e-mail address					
Has this individual consented to sharing their details on this form?		YES	☒	NO	☐
Are you in receipt of a KESS scholarship?		YES	☒	NO	☐
Is your research externally funded		YES	☒	NO	☐
Are you specifically employed to undertake this research in either a paid or voluntary capacity?	Voluntary	YES	☐	NO	☒
	Employed	YES	☒	NO	☐
Is the research being undertaken within an existing UWTSD Athrofa Professional Learning Partnership (APLP)	If YES then the permission question below does not need to be answered.	YES	☐	NO	☒
Permission to undertake the research has been provided by the partner organisation	(If YES attach copy) If NO the application cannot continue	YES	☒	NO	☐

Where research activity is carried out in collaboration with an external organisation

Does this organisation have its own ethics approval system?	YES	☐	NO	☒
If Yes, please attach a copy of any final approval (or interim approval) from the organisation				

SECTION E: Details of Research Activity

Indicative title:	Cancer, Coping & Covid-19: Exploring the impact of COVID-19 on engagement with and need for psychosocial support in Wales: a longitudinal study.		
Proposed start date:	1st July 2020	Proposed end date:	March 2021

Introduction to the Research (maximum 300 words)

Ensure that you write for a Non-Specialist Audience when outlining your response to the three points below:

Purpose of Research Activity

Proposed Research Question

Aims of Research Activity

Objectives of Research Activity

Demonstrate, briefly, how Existing Research has informed the proposed activity and explain

What the research activity will add to the body of knowledge

How it addresses an area of importance.

Purpose of Research Activity

The proposed project represents the final study of a KESS-funded PhD project in partnership with Tenovus Cancer Care, the overall aim of which being to conduct a psychosocial evaluation of an existing Tenovus initiative to enable the piloting and evaluation of the Psychosocial Cancer Evaluation Toolkit and interface in a real-life setting. Bearing in mind the current COVID-19 crisis which has necessitated some adaptations to the original plan for the third study (discussed and approved by Tenovus Cancer Care) This current study builds on the previous work conducted for the PhD exploring the psychosocial impact of cancer and evaluating the support that people with cancer engage with, with a particular focus in the present application on the additional impact of COVID-19. Ethical approval was sought on 30/07/18 for phase one and two of the project and it was made clear that another ethics application would be made for the final study due to the natural evolution of the project.

The psychological impact of living with a cancer diagnosis is well recognised, and with more people living longer with cancer than ever before, the need to ensure appropriate psychosocial support to individuals with cancer remains vital (Deimling et al., 2006; Guner et al., 2006). The impact of the COVID-19 epidemic on individuals with cancer in Wales and elsewhere has been significant, both in terms of their access to clinical care but also the additional stress, anxiety and uncertainty caused by the threat of COVID-19 and the national lockdown (Blood Cancer UK, 2020; CRUK, 2020; Guan et al., 2019; Liang et al., 2020; UKCCMP, 2020). The psychological impact of COVID-19 on those affected by cancer is not only being seen now but is expected to increase dramatically over the next six months (Torales et al., 2020), and yet

those in a position to provide psychological support are themselves struggling to deliver this effectively given the COVID-19 lockdown and social distancing measures.

(this box should expand as you type)

Research Question

The purpose of this study therefore is to explore the extent to which the psychosocial support needs of individuals with cancer in Wales during COVID-19 are being met currently, and to identify the best ways of supporting those who need it most into the future.

(this box should expand as you type)

Aims of Research Activity

The overall aim of this study is to explore the impact of COVID-19 on the current and future psychosocial support needs of individuals with cancer in Wales.

Objectives of Research Activity

to identify key predictors of psychological distress and quality of life in individuals living with cancer in Wales during COVID-19

to evaluate the level of current and ongoing unmet support needs in individuals living with cancer in Wales during COVID-19

to identify the future psychosocial support needs of the most psychologically vulnerable and the extent to which current provision is likely to be able to meet these needs

(this box should expand as you type)

Proposed methods (maximum 600 words)

Provide a brief summary of all the methods that may be used in the research activity, making it clear what specific techniques may be used. If methods other than those listed in this section are deemed appropriate later, additional ethical approval for those methods will be needed.

The study will employ a longitudinal online questionnaire, capturing quantitative and qualitative data over a six month period between July 2020 and December 2020. Given the need to capture data from a Wales-wide population in a relatively short space of time, and with COVID-19 restrictions still in place, the use of an online questionnaire is the ideal methodology to

collect data from the target population (Horevoorts et al., 2015). The online survey will include quantitative and qualitative measures to ensure breadth and depth of experiences are captured during this unprecedented period. The online study will be provided via the Qualtrics survey system through the medium of English and Welsh (participants will be able choose their language to respond in).

Baseline measures

The baseline survey will capture the following basic demographic data: age, gender, marital status, education level, and children. Clinical data collected will include cancer type, years since diagnosis, treatment stage.

Psychological measures at baseline will include the following:

Unmet Needs: The primary outcome measure is the *Survivor Unmet Needs Survey – Short form* (SUNS-SF; Campbell et al., 2014), a 30-item scale consisting of four subscales measuring: *information, financial concerns, access and continuity of care* and *relationships and emotional health* which all contribute to the overall measurement of unmet needs in a general cancer population.

COVID-specific distress: *The Impact of Event Scale (IES; Horowitz et al., 1979)* will be used as a predictor variable and will consist of 15 items capturing the frequency of participants' intrusive thoughts about COVID-19, and attempts to avoid these thoughts. The IES allows the calculation of a total score and separate intrusion and avoidance subscales scores. Horowitz[35] identified thresholds for low, medium, and high symptom levels corresponding to levels of clinical concern using the IES total score: low < 8.5; medium = 8.6 to 19.0; and high > 19. The IES has been used as a measure of psychological distress particularly post traumatic stress in a number of studies and has consistently demonstrated good internal consistency and test re-test reliability amongst cancer populations (Kent et al, 2000; Thewes et al., 2001).

Quality of Life: The *Functional Assessment for Cancer Therapy – General* (FACT-G; Cella & Tuskey, 1993). This is a 33-item questionnaire measuring overall quality of life in a general cancer population through five subscales including; *physical, functional, social, emotional* and *relationship with doctor.* An individual is given a score for each subscale and a total score to indicate overall quality of life.

Loneliness: The *Cancer Loneliness Scale* (CLS; Adams et al., 2017) will be used as a predictor variable and is a 7-item unidimensional scale measuring loneliness following a cancer diagnosis. This scale specifically focuses on how often individuals feel lonely, or isolated at different points of their cancer journey and is considered a key variable to include given the lockdown.

Illness Perceptions: *The Brief Illness Perceptions Questionnaire (Broadbent et al., 2006) is* a nine-item scale designed to rapidly assess the cognitive and emotional representations of

illness as identified in Leventhal's self regulatory model and is considered ideal for repeated measures designs with vulnerable populations.

Process measures: Support Needs: At each time –point participants will be asked to identify the forms of support they have accessed over the last month from a range of clinical and psychosocial support initiatives available in Wales.

Free text data: At each time point participants will be given the opportunity to provide free text data in relation to 1) the impact of COVID-19 and 2) their met and unmet support needs. The provision of free text data in studies exploring the psychological impact of coping, uncertainty and anxiety has been shown to be a valuable mechanism to capture participants' experiences in greater depth (Hilgart, Phelps et al., 2012).

(this box should expand as you type)

Location of research activity Identify all locations where research activity will take place.
The study will be conducted online using Qualtrics online survey platform hosted by the Psychology & Counselling Discipline at UWTSD and will focus on individuals residing in Wales. (this box should expand as you type)
Research activity outside of the UK If research activity will take place overseas, you are responsible for ensuring that local ethical considerations are complied with and that the relevant permissions are sought. Specify any local guidelines (e.g. from local professional associations/learned societies/universities) that exist and whether these involve any ethical stipulations beyond those usual in the UK (provide details of any licenses or permissions required). Also specify whether there are any specific ethical issues raised by the local context in which the research activity is taking place, for example, particular cultural and/or legal sensitivities or vulnerabilities of participants.
(this box should expand as you type)

Use of documentation not in the public domain: Are any documents NOT publicly available?	NO	☒
	YES	☐
If Yes, please provide details here of how you will gain access to specific documentation that is not in the public domain and that this is in accordance with prevailing data protection law of the country in question and England and Wales. *(this box should expand as you type)*		

SECTION F: Scope of Research Activity

Will the research activity include:	YES	NO
Use of a questionnaire or similar research instrument?	☒	☐
Use of interviews?	☐	☒
Use of diaries?	☐	☒
Participant observation with their knowledge?	☐	☒

Participant observation without their knowledge?	☐	☒
Use of video or audio recording?	☐	☒
Access to personal or confidential information without the participants' specific consent?	☐	☒
Administration of any questions, test stimuli, presentation that may be experienced as physically, mentally or emotionally harmful / offensive? Participants will be asked about their cancer experience during covid-19 which has the potential for distress. Details on how this will be mitigated are listed in Section H.	☒	☐
Performance of any acts which may cause embarrassment or affect self-esteem?	☐	☒
Investigation of participants involved in illegal activities?	☐	☒
Use of procedures that involve deception?	☐	☒
Administration of any substance, agent or placebo?	☐	☒
Working with live vertebrate animals?	☐	☒
Other primary data collection methods, please explain in this box For example, 'focus groups'. Please indicate the type of data collection method(s) in this box and tick the accompany box.		
Details of any other primary data collection method: (this box should expand as you type)	☐	☐

If NO to every question, then the research activity is (ethically) low risk and may be exempt from some of the following sections (please refer to Guidance Notes).

If YES to any question, then no research activity should be undertaken until full ethical approval has been obtained.

SECTION G: Intended Participants

Who are the intended participants:	YES	NO
Students or staff at the University?	☒	☐
Adults (over the age of 18 and competent to give consent)?	☒	☐
Vulnerable adults?	☐	☒
Children and Young People under the age of 18? (Consent from Parent, Carer or Guardian will be required)	☐	☒
Prisoners?	☐	☒
Young offenders?	☐	☒

Those who could be considered to have a particularly dependent relationship with the investigator or a gatekeeper?	☐	☒
People engaged in illegal activities?	☐	☒
Others (please identify specifically any group who may be unable to give consent) please indicate here and tick the appropriate box.		
Other – please indicate here: (this box should expand as you type)	☐	☐

Participant numbers and source Provide an estimate of the expected number of participants. How will you identify participants and how will they be recruited?	
How many participants are expected?	Previous research with the same target population and similar outcomes have a sample size ranging from 100-400 participants. Using a rule of thumb for a regression analysis (N>104+k) a target population of at least 136 is appropriate. (VanVoorhis & Morgan, 2007) *(this box should expand as you type)*
Who will the participants be?	The following inclusion and exclusion criteria have been identified to describe the target population for this study. Inclusion criteria: Males and females over the age of 18 in Wales who have a current diagnosis of cancer Residing in Wales during COVID-19 Are receiving, or have received, cancer-related clinical care and/or psychosocial support from organisations in Wales within the last six months. Exclusion criteria: Individuals under the age of 18 Individuals with significant comorbid psychological or physical health conditions. *(this box should expand as you type)*
How will you identify the participants?	Participants will be recruited through an online advert (approved by supervisory team) inviting individuals who fit the inclusion criteria to take part in a study exploring their experiences during the COVID-19 pandemic. As this is an online study, online methods of distribution will be used. The advert will be sent out on the UWTSD Psychology Twitter account and Tenovus Cancer Care Research Team twitter/facebook account and research

	mailing list. Once approved by the supervisory team it will also be shared on the researcher's twitter and Facebook accounts. *(this box should expand as you type)*

Information for participants:	YES	NO	N/A
Will you describe the main research procedures to participants in advance, so that they are informed about what to expect?	☒	☐	☐
Will you tell participants that their participation is voluntary?	☒	☐	☐
Will you obtain written consent for participation?	☒	☐	☐
Will you explain to participants that refusal to participate in the research will not affect their treatment or education (if relevant)?	☒	☐	☐
If the research is observational, will you ask participants for their consent to being observed?	☐	☐	☒
Will you tell participants that they may withdraw from the research at any time and for any reason?	☒	☐	☐
With questionnaires, will you give participants the option of omitting questions they do not want to answer?	☒	☐	☐
Will you tell participants that their data will be treated with full confidentiality and that, if published, it will not be identifiable as theirs?	☒	☐	☐
Will you debrief participants at the end of their participation, in a way appropriate to the type of research undertaken?	☒	☐	☐
If NO to any of above questions, please give an explanation			
As this is an online study written consent takes the form of an agreement via tick boxes, seen as an acceptable alternative when carrying out online research (BPS Ethics Guidelines for Internet-Mediated Research, 2017) *(this box should expand as you type)*			

Information for participants:	YES	NO	N/A
Will participants be paid?	☐	☒	☐
Is specialist electrical or other equipment to be used with participants?	☐	☒	☐
Are there any financial or other interests to the investigator or University arising from this study?	☐	☒	☐
Will the research activity involve deliberately misleading participants in any way, or the partial or full concealment of the specific study aims?	☐	☒	☐
If YES to any question, please provide full details			
  (this box should expand as you type)			

SECTION H: Anticipated Risks

Outline any anticipated risks that may adversely affect any of the participants, the researchers and/or the University, and the steps that will be taken to address them.

If you have completed a full risk assessment (for example as required by a laboratory, or external research collaborator) you may append that to this form.

Full risk assessment completed and appended?	Yes	☐
	No	☒

Risks to participants

For example: emotional distress, financial disclosure, physical harm, transfer of personal data, sensitive organisational information

Risk to Participant:	*How will you mitigate the Risk to Participant*
Potential for distress: participants will be asked about their cancer experience during the COVID-19 pandemic. This includes acting about their physical health status and mental health. Some of these questions may be distressing to discuss and asking about them in reference to the COVID-19 pandemic may make them even more distressed. Informed online consent: participants will be asked to read a study information sheet detailing the aims of the study and consent to sharing sensitive/special category information. *(this box should expand as you type)*	All planned study procedures have been considered in relation to the British Psychological Society's Code of Human Research Ethics (2010), and BPS Guidance for Internet Mediated Research (2017) good practice guidelines for online informed consent processes have been followed. The project's focus is on the subject of cancer and therefore carries a risk of emotional distress, however there are protocols in place to help minimise this as much as possible. Finally, any personal data collected will be handled in line with the GDPR (2016) and UWTSD data management policy. Please see section I for further details on how the risks will be mitigated through informed consent and debrief processes. Potential for distress: Participants will be provided with an online study information sheet detailing that they will be asked about the psychosocial aspects of cancer experience and in relation to the COVID-19 pandemic. Participants will be told that their participation is entirely voluntary and they can withdraw at any time by closing the browser/emailing the researcher to withdraw their data. If this occurs and the participant has contacted the researcher they will be supported appropriately with sign-posting to cancer support services.

	Participants will be made aware that they will be able to leave questions out if they do not wish to answer them and that they can stop at any time by closing the browser. Participants will be informed that taking part in the study will have no impact or relation to any clinical care they may be receiving now or in the future. For the validated measures, consideration has been given to the wording of the questions to ensure they are appropriate for the study. Scales have been chosen for specificity, sensitivity and to ensure no unnecessary or overly intrusive questions are asked. The chosen measures are validated scales which have been used regularly in psychosocial cancer research as documented through a systematic review completed as part of this PhD. Once participants decide to take part and subsequently complete the online questionnaire, they will be provided with an online debrief with details of the researcher, director of studies and sign-posting details for further support from Tenovus Cancer Care and CISS, should they need it. They will also be reminded that they can withdraw their data from the study. Participants will not be asked to disclose any financial information and are not at risk of any physical harm whilst taking part in the study. *(this box should expand as you type)*
If research activity may include sensitive, embarrassing or upsetting topics (e.g. sexual activity, drug use) or issues likely to disclose information requiring further action (e.g. criminal activity), give details of the procedures to deal with these issues, including any support/advice (e.g. helpline numbers) to be offered to participants. Note that where applicable, consent procedures should make it clear that if something potentially or actually illegal is discovered in the course of a project, it may need to be disclosed to the proper authorities	
As detailed above, this study has the potential to cause distress to the participant as it is asking about their cancer and psychological wellbeing and collecting personal information such as demographics and email addresses. Following the procedures above for adequate study	

information and informed consent, participants will be fully aware of what they will be asked about should they take part in the study and that they can stop at any time with no explanation.

The potential for harm or increasing psychological distress in study participants must always be minimised as far as possible. Given this study will be conducted during the pandemic and in direct relation to the potential impact of the pandemic, potential for distress could be higher, signposting to relevant bodies is very important. Following the end of the questionnaire participants will be provided with the following details:

Zoe Cooke (PhD Researcher)

Zoe.cooke@uwtsd.ac.uk

Dr Ceri Phelps (Director of Studies)

Ceri.phelps@uwtsd.ac.uk

Tenovus Cancer Care Support Line (Mon-Fri 9am-5pm/ Weekends 10am-1pm)

0808 808 1010

Cancer Information Support Services (CISS)

Swansea: 01792 655 025

Neath Port Talbot: 01639 642 333

Risks to investigator

For example: personal safety, physical harm, emotional distress, risk of accusation of harm/impropriety, conflict of interest

Risk to Investigator:	*How will you mitigate the Risk to Investigator:*
As this is an online study there is no direct risk to the investigators; however, there is the potential for researchers to be contacted via email or in person by participants. *(this box should expand as you type)*	Only university email addresses will be provided as points of contact The researcher (Zoe Cooke) has experience of conducting online research and will be guided by Dr Ceri Phelps. Both are experienced at dealing with online study queries and able to make sound judgments regarding responses to requests/queries

	The planned empirical studies involve limited direct individual personal contact with potentially vulnerable participants, and therefore minimal risk to the researcher is expected. However, the researcher has experience of working with vulnerable adults in mental health and social care settings and has undergone several training courses such as; mental health awareness, dementia and first aid. The researcher also has a full DBS as part of being a PhD student at UWTSD. Specifically in relation to this project, the principal researcher (PhD Student) has undergone an induction process at Tenovus Cancer Care and has previous experience of conducting research with a vulnerable population including those with cancer. If issues are raised that, in the judgment of the researcher and supervisory team, constitute potential harm to either participants or researcher, the study will be immediately suspended whilst further investigation is carried out Should any distress occur as a consequence of engaging with individuals who could potentially be distressed or upset, a weekly meeting with the Director of Studies during the data collection phase of each study will enable the PhD student to debrief with the Director of Studies who has significant experience of researching cancer populations. *(this box should expand as you type)*
University/institutional risks For example: adverse publicity, financial loss, data protection	
Risk to University: There are no anticipated risks to the university	*How will you mitigate the Risk to University:* In order to minimise any potential institutional risks, the proposed research will adhere to

(this box should expand as you type)	University Research Ethics & Integrity Code of Practice and at all times. Both the PhD student and Director of Studies have previous experience of researching vulnerable populations. The principles of NHS research ethics and governance will be applied at all stages of the research to ensure ultimate protection from any potential institutional harm. The director of studies is a HCPC registered Health Psychologist with over fifteen years' experience of leading psychosocial intervention studies with cancer populations. No risks are predicted to occur to the university due to all research following ethical requirements and good research practice at all times. The UWTSD data protection policy will also be followed throughout ensuring data protection is upheld. Therefore, any risks are unlikely but will be monitored closely throughout the PhD and reported immediately to the Director of Studies. *(this box should expand as you type)*

Disclosure and Barring Service			
If the research activity involves children or vulnerable adults, a Disclosure and Barring Service (DBS) certificate must be obtained before any contact with such participants.	YES	NO	N/A
Does your research require you to hold a current DBS Certificate?	☐	☒	☐

SECTION I: Feedback, Consent and Confidentiality

Feedback What de-briefing and feedback will be provided to participants, how will this be done and when?
Debriefing: At the end of the study participants will be presented with an online debrief which they can request a copy of directly from the researcher. It is important to try and ensure the participant does not feel distressed following the completion of the study. The debrief will explain exactly why the study is being conducted and should they wish to receive a summary of the findings they can do so. Participants will be provided with the following contact details and sign-posting information following the end of the questionnaire: Zoe Cooke (PhD Researcher) Zoe.cooke@uwtsd.ac.uk Dr Ceri Phelps (Director of Studies) Ceri.phelps@uwtsd.ac.uk Tenovus Cancer Care Support Line (Mon-Fri 9am-5pm/ Weekends 10am-1pm) 0808 808 1010 Cancer Information Support Services (CISS) Swansea: 01792 655 025 Neath Port Talbot: 01639 642 333 Participants will be reminded that they can contact the research or director of studies using these details if they want to discuss any issues or seek any support. They will also be reminded that their data will; be anonymised and only accessible to the researcher and director of studies, will not impact on any clinical care now or in the future and will not be able to be linked back to them when it is written up for the purpose of the thesis or potential publications. *(this box should expand as you type)*
Informed consent Describe the arrangements to inform potential participants, before providing consent, of what is involved in participating. Describe the arrangements for participants to provide full consent before

data collection begins. If gaining consent in this way is inappropriate, explain how consent will be obtained and recorded in accordance with prevailing data protection legislation.

Informed online consent:

The procedures will follow good practice guidelines from NHS ethics processes. The PhD student and DoS have significant previous experience with successful NHS ethics applications, study protocols and good practice procedures.

An online consent form will be presented to participants following the study information sheet. It will set out the participant's right to withdraw their data and how it will be stored and shared.

Participants will need to be over 18 and able to provide their consent to take part in the study.

Participants will be asked for their email address when they take part in the study in order to track changes over time, therefore they will need to consent to being contacted via email for data collection purposes. Participants will be made aware that this information is stored securely and will not be shared with anyone else or used for any other purpose.

All participants will be given opportunity to provide informed consent in a free manner, with the ability to withdraw their consent/request the destruction of their data at any point during the data gathering phase by emailing the researcher and provided information that will allow their data to be sourced and deleted.

Consent will be acquired online through Qualtrics where participants will have to electronically select boxes to indicate consent. A thorough informed consent process will therefore include: 1) providing participants with a clearly written online information sheet detailing the information they need in order to decide whether to take part in the study 2) making it clear that participation is voluntary and that they can change their mind at any time by closing the browser or contacting the researcher with the relevant information to seek out their data to be deleted 3) making it clear that the decision whether or not to take part in the study will have no impact on any clinical care that they may be receiving now or in the future and 4) confirming that they have read and understood the study information sheet and if they have any further questions prior to taking part they can contact the researcher directly.

(this box should expand as you type)

Confidentiality / Anonymity

Set out how anonymity of participants and confidentiality will be ensured in any outputs. If anonymity is not being offered, explain why this is the case.

The online participant information sheet makes it clear to all participants that they have a right to expect that information they provide when completing the study will be treated confidentially in line with the General Data Protection Regulation (GDPR, 2016), Data Protection Act (2018) and UWTSD Data Management Policy. It will also make it clear that any data collected during the research study will be anonymised and will not be identifiable to any individual participant. The

study will be anonymous but will collect basic demographics and clinical data. Participants will be asked for an email address in order to complete follow-up questionnaires, participants will be assured that this information will not be shared with anyone other than the researcher. Study procedures for the secure storage of data will follow good practice guidelines. Quantitative data will be downloaded from Qualtrics into the statistical analysis package SPSS and will be anonymised for the purpose of evaluation. The SPSS file will be stored on a password protected computer and only the primary researcher and main supervisor will have access. Any identifiable information such as email addresses will be stored separately with a link to the individual ID number, kept in a password protected file which only the primary researcher will have access to. Data will not be able to be traced back to any individual when it is written up for the purpose of thesis submission and potential future journal publications.

(this box should expand as you type)

SECTION J: Data Protection and Storage

In completing this section refer to the University's Research Data Management Policy and the extensive resources on the University's Research Data Management web pages (http://uwtsd.ac.uk/library/research-data-management/).

Does the research activity involve personal data (as defined by the General Data Protection Regulation 2016 "GDPR" and the Data Protection Act 2018 "DPA")?	YES	NO
"Personal data" means any information relating to an identified or identifiable natural person ('data subject'). An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.	☒	☐
If YES, provide a description of the data and explain why this data needs to be collected:		
Individuals will be asked about their cancer status, time since diagnosis and type of treatment and will be asked to provide an email address. Asking about their cancer is essential to the study as this is what is being explored. Asking for an email address is required in order to be able to track participants over time given that this is a longitudinal study. *(this box should expand as you type)*		
Does it involve special category data (as defined by the GDPR)?	YES	NO

"Special category data" *means sensitive personal data consisting of information as to the data subjects' –* *(a) racial or ethnic origin,* *(b) political opinions,* *(c) religious beliefs or other beliefs of a similar nature,* *(d) membership of a trade union (within the meaning of the Trade Union and Labour Relations (Consolidation) Act 1992),* *(e) physical or mental health or condition,* *(f) sexual life,* *(g) genetics,* *(h) biometric data (as used for ID purposes),*	☒	☐
If YES, provide a description of the special category data and explain why this data needs to be collected:		
e) *physical or mental health or condition* This study is exploring the psychosocial impact of cancer during the COVID-19 pandemic and it is therefore essential to collect data relating to their cancer status, quality of life and psychological well-being. This information will be completely anonymised for the purpose of analysis and publication. *(this box should expand as you type)*		

Will the research activity involve storing personal data and/or special category data on one of the following:	YES	NO
Manual files (i.e. in paper form)?	☐	☒
University computers?	☒	☐
Private company computers?	☐	☒
Home or other personal computers?	☐	☒
Laptop computers/ CDs/ Portable disk-drives/ memory sticks?	☐	☒
"Cloud" storage or websites?	☒	☐
Other – specify:	☐	☐
For all stored data, explain the measures in place to ensure the security of the data collected, data confidentiality, including details of password protection, encryption, anonymisation and pseudonymisation:		
Data will be collected via the Qualtrics online survey system, and will be stored in their cloud-based repository as data is collected. Whilst the Qualtrics system has the ability to store identifying		

features of the web source (IP addresses, location, etc.) this will be turned off prior to data collection as there is no need for these data to be collected for the current study. Data that is downloaded from Qualtrics will be stored in a password protected file on the university network and will be anonymised within 48 hours of it being downloaded.

(this box should expand as you type)

All Data Storage

Will the research activity involve any of the following activities:	YES	NO
Electronic transfer of data in any form?	☒	☐
Sharing of data with others at the University?	☒	☐
Sharing of data with other organisations?	☐	☒
Export of data outside the European Union or importing of data from outside the UK?	☐	☒
Use of personal addresses, postcodes, faxes, emails or telephone numbers?	☒	☐
Publication of data that might allow identification of individuals?	☐	☒
Use of data management system?	☒	☐
Data archiving?	☒	☐

If YES to any question, please provide full details, explaining how this will be conducted in accordance with the GDPR and DPA (and/or any international equivalent):

Participants will be fully informed on the data being collected about them, how it will be stored and for what length of time and details as to how they can withdraw/access this data will be contained within the study information sheet, consent form and study debrief.

Data will be transferred from the Qualtrics cloud system to a secure university network on a weekly basis. Raw data will only be accessible to Zoe Cooke and once this is downloaded from Qualtrics it will be anonymised within 48 hours. Two members of the discipline of Psychology and Counselling who have administrator rights, will have limited access to the data on Qualtrics but will be unable to identify anyone.

Sharing with other organisations: the data will be collected using Qualtrics which is a data collection software, this will then be electronically transferred to a secure university network that is password protected. The raw data will not be shared with any organisations outside the university. The anonymised final data will be shared for the purposes of writing up the PhD thesis and potential publication.

Once data is downloaded from Qualtrics onto the secure university network it will be stored in a password protected SPSS file with no identifying features. Any identifiable information such as email address will be stored in a separate password protected document with only the researcher Zoe Cooke and Dr Ceri Phelps (DoS) who will have access to it.

Data will be collected, handled and appropriately stored in accordance with The General Data Protection Regulation (GDPR, 2016), UWTSD Group Data Protection Policy and Research Data Management Policy.

Article 5 of GDPR states that data must be '*kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes subject to implementation of the appropriate technical and organisational measures required by the GDPR in order to safeguard the rights and freedoms of individuals…*
…processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures.'

Section 4 of the Research Data Management Policy will be followed at all times. Specifically Section 4.3 stating that all data collected must be:
Accurate and reliable
Identifiable, retrievable and accessible
Retained in a safe and secure manner and compliant with legal requirements
Additionally Section 4.14 details appropriate data storage and retainment as informed by the RCUK Guidance on best practice in the management of research data' the Research Councils expect that findings should still be accessible for at least 10 years after publication.

To summarise:

Storage: Data will be downloaded from Qualtrics and stored in a password protected file on the secure university network, once downloaded data will be anonymised within 48 hours meaning any identifiable information will be removed and stored in separate password protected document on the university network. There will be no hard copy data as the study is completely online so all electronic data will be stored in a password protected file on a university computer which is also password protected.

Data sharing: Data that is collected on Qualtrics will only be accessible to Zoe Cooke as the main researcher and the two members of the discipline of Psychology and Counselling who have admin rights on Qualtrics (Dr Paul Hutchings and Katie Sullivan) although the administrators have limited access to this data. Only anonymised data will be used for the purposes of analysis and publication with no way of identifying individual participants. Only the PhD Student and lead supervisor will have access to the raw data once downloaded from Qualtrics.

(this box should expand as you type)

List all who will have access to the data generated by the research activity:

Raw Data: Miss Zoe Cooke and DoS Dr Ceri Phelps (UWTSD)

(this box should expand as you type)
List who will have control of, and act as custodian(s) for, data generated by the research activity:
Miss Zoe Cooke and DoS Dr Ceri Phelps (UWTSD) *(this box should expand as you type)*
Give details of data storage arrangements, including security measures in place to protect the data, where data will be stored, how long for, and in what form. Will data be archived – if so how and if not why not.
Data will initially be collected and stored on the Qualtrics cloud storage facility allocated to Yr Athrofa before being downloaded on a weekly basis by Zoe Cooke. Data will be downloaded onto a password protected file on the university network. Raw data will be stored on the password-protected university network assigned to Zoe Cooke with access only to Zoe Cooke and Dr Ceri Phelps (DoS). Data will be stored in SPSS format as a password protected file. This data will be anonymised within 48 hours when downloaded for the purpose of evaluation. Qualtrics cloud storage can only be accessed by the person who creates the study on Qualtrics and also deleted by that person. In this instance that is the PhD student Zoe Cooke. Data will be deleted from the Qualtrics cloud storage once placed in the UWTSD Data repository at the end of the data collection period (Jan 2021). Data will be retained on the repository for at least ten years, as per the guidance from RCUK. *(this box should expand as you type)*
Please indicate if your data will be stored in the UWTSD Research Data Repository (see https://researchdata.uwtsd.ac.uk/). If so please explain. (*Most relevant to academic staff*)
Data will be stored in SPSS format as a password protected file. Upon completion of data collection, and once the research team are satisfied that no possible identifying materials are contained within the dataset, the data file will be stored in the UWTSD data repository. *(this box should expand as you type)*

Confirm that you have read the UWTSD guidance on data management (see https://www.uwtsd.ac.uk/library/research-data-management/)	YES	☒
	NO	☐
Confirm that you are aware that you need to keep all data until after your research has completed or the end of your funding	YES	☒
	NO	☐

SECTION K: Declaration

The information which I have provided is correct and complete to the best of my knowledge. I have attempted to identify any risks and issues related to the research activity and acknowledge my obligations and the rights of the participants.

In submitting this application I hereby confirm that I undertake to ensure that the above named research activity will meet the University's Research Ethics and Integrity Code of Practice which is published on the website: https://www.uwtsd.ac.uk/research/research-ethics/		
Signature of applicant:		Date:08/06/2020

For STUDENT Submissions:

Director of Studies/Supervisor:	Dr Ceri Phelps	Date: 11/09/2020
Signature:		

For STAFF Submissions:

Academic Director/ Assistant Dean:		Date:
Signature:		

Checklist: Please complete the checklist below to ensure that you have completed the form according to the guidelines and attached any required documentation:

☒	I have read the guidance notes supplied before completing the form.
☒	I have completed ALL RELEVANT sections of the form in full.
☒	I confirm that the research activity has received approval in principle
☐	I have attached a copy of final/interim approval from external organisation (where appropriate)
☐	I have attached a full risk assessment (and have NOT completed Section H of this form) (where appropriate) *ONLY TICK IF YOU HAVE ATTACHED A FULL RISK ASSESSMENT*

☒	I understand that it is my responsibility to ensure that the above named research activity will meet the University's Research Ethics and Integrity Code of Practice.
☒	I understand that before commencing data collection all documents aimed at respondents (including information sheets, consent forms, questionnaires, interview schedules etc.) must be confirmed by the DoS/Supervisor, module tutor or Academic Director.
☒	I have deleted the guidance notes before submitting the PG2 for consideration

RESEARCH STUDENTS AND STAFF ONLY

All communications relating to this application during its processing must be in writing and emailed to pgresearch@uwtsd.ac.uk , with the title 'Ethical Approval' followed by your name.

You will be informed of the outcome of your claim by email; therefore **it is important that you check your University and personal email accounts regularly**.

STUDENTS ON UNDERGRADUATE OR TAUGHT MASTERS PROGRAMMES should submit this form (and receive the outcome) via systems explained to you by the supervisor/module leader.

This form is available electronically from the Academic Office web pages:
https://www.uwtsd.ac.uk/academic-office/appendices-and-forms/

Application Process

All staff research projects and all research students must submit the Ethical Approval Form to the University Research Ethics Committee via the Academic Office (pgresearch@uwtsd.ac.uk). Staff research directly in relation to personal study for taught undergraduate or Masters programmes should be submitted via the Institute procedures explained below.

Taught masters and taught undergraduate research Ethical Approval Forms are considered within Institutes. Institutes will provide details of the specific processes for this. Where the Ethical issues within any single ethical application are of particular concern the Institute will refer these to the University Research Ethics Committee. Any student activity that involves

the collection of primary data needs to undergo Ethical approval, this includes assignment work as well as dissertations.

Appendix B – Delphi study materials

Delphi study information sheet

Exploring how best to measure the impact of cancer support services: an online consensus study

Study information sheet

I am a PhD student at the University of Wales Trinity Saint David (UWTSD). I would like to invite you to take part in an online study. Please read the following information carefully. It will tell you what the study is about and why we have asked to you take part. Please remember that taking part is voluntary so it is up to you to decide whether or not to take part. Thank you for taking the time to read this.

Zoe Cooke (PhD Student)

What is the purpose of the study?

This online survey is the first study of a PhD funded by KESS in partnership with Tenovus Cancer Care. The aim of this PhD is to work out the best way for Tenovus Cancer Care to show the impact their services have on the mental health and wellbeing of people affected by cancer. This should help Tenovus Cancer Care decide whether they are providing the best support for people affected by cancer.

The purpose of this study is to try and identify what types of support individuals affected by cancer feel are important to them. I also want to find out the best ways of measuring whether these types of support are helpful. To do this I am asking a range of people to take part in an online survey. I am asking individuals affected by cancer and people who provide care and support (doctors, nurses, charities) to take part in this study.

Why have I been asked to take part?

Everyone who has had some experience of cancer has important knowledge to share with us. If you have had cancer, are supporting a family member or friend with cancer, or working as a professional or volunteer in cancer care, then we consider you to be an expert. We are not asking you to evaluate any specific care received as an NHS patient.

What will I be asked to do if I take part?

If you decide to take part you will need to follow the arrows at the bottom of the page to the consent form. After signing the consent form you will be asked to complete the first of two surveys. The second survey will be sent to you via email in a few weeks time. The surveys will ask you what you think about cancer support services. We want to know what issues are important or relevant to ask about when working out if a cancer support service has had an impact on a person. Answers from the first survey will help construct the second survey. This is because we are looking at how much people agree on the importance and relevance of these items. If an item on the first survey is rated very low on importance or relevance by over 70% of participants, it will not be included in the second survey because consensus (agreement) has been reached.

If you decide to take part, you will need to be happy to provide me with an email address. This is so that we can send you the link to the second survey. Each survey should take between 10-15 minutes to complete. We will never use your email address to get in touch with you about anything else and we won't share it with any third parties.

Are there any risks involved?

The project has received full ethical approval from UWTSD. All information collected by the researcher will remain confidential and your identity and responses will remain anonymous to other participants. It is really important for you to know that no one else will know who you are or be able to work it out. Should taking part in the study cause any discomfort or distress please contact the researcher. Please also remember you do not have to take part and can stop at any time by closing the browser window.

Should you need any additional support you can get in touch with the Tenovus Cancer Care Support Line on 0808 808 1010 which is a free service.

What happens at the end of the study?

The information collected in this study will be used to help us a develop a toolkit to help Tenovus Cancer Care evaluate future services more effectively.

This project is part of a 3 year funded PhD and your information will need to be kept until the end of the PhD. Once you have completed the study your information will be stored securely in an encrypted computer file. Once the project has finished all personal information will be deleted. The results of this study may be published in research journals and presented at relevant conferences. Please know that your information will remain anonymous throughout. We stick to strict data protection rules and can give you more details about this if you would like.

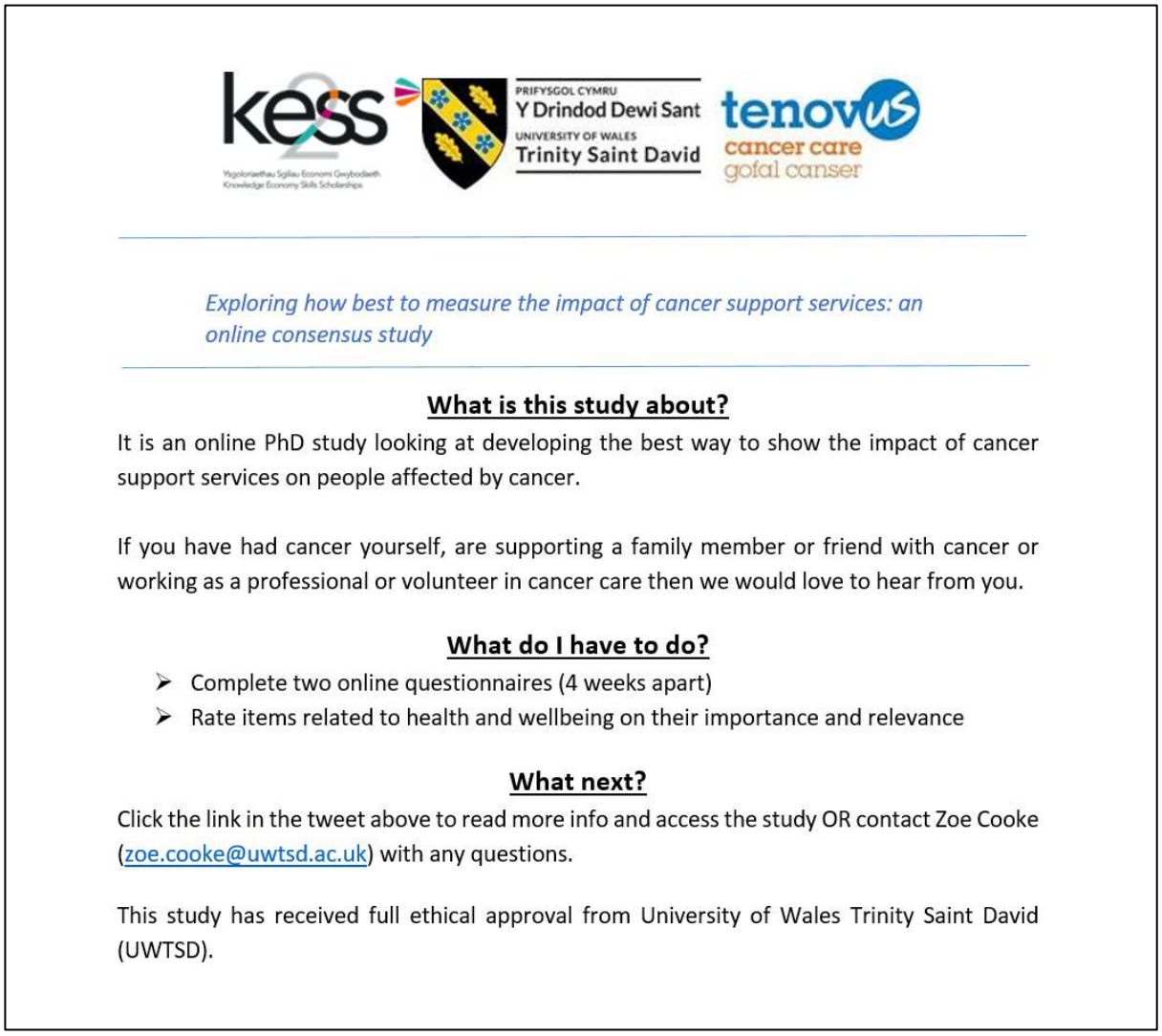
If you are unsure about anything you have read here, please get in touch with me on the details below. Once again thank you for taking the time to read this information.

PhD Student – Zoe Cooke (zoe.cooke@uwtsd.ac.uk)

Supervisor – Dr Ceri Phelps (ceri.phelps@uwtsd.ac.uk)

Twitter advert

"Please RT: Do you have experience of cancer and/or work in the cancer field? Your opinion is really important and we would love to hear from you! Please take part in my PhD study exploring the evaluation of cancer support services''



Exploring how best to measure the impact of cancer support services: an online consensus study

What is this study about?

It is an online PhD study looking at developing the best way to show the impact of cancer support services on people affected by cancer.

If you have had cancer yourself, are supporting a family member or friend with cancer or working as a professional or volunteer in cancer care then we would love to hear from you.

What do I have to do?

- Complete two online questionnaires (4 weeks apart)
- Rate items related to health and wellbeing on their importance and relevance

What next?

Click the link in the tweet above to read more info and access the study OR contact Zoe Cooke (zoe.cooke@uwtsd.ac.uk) with any questions.

This study has received full ethical approval from University of Wales Trinity Saint David (UWTSD).

Delphi questionnaire including consent – taken from Qualtrics

I consent to the following - I have read and understood the information on the previous page - I am 18 years or older - I understand my identity will remain unknown to other participants and my information will comply with current data protection legislation - I agree for the researcher to contact me via email for the purpose of the additional study rounds	
Please enter your email address so the researcher can contact you for the next round of questions	
Please tell us your age	
Please tell us your gender	• Male • Female • Other • Prefer not to say
Please select the option which best represents your experience	• Have experienced cancer personally • Supported a family member and/or friend with cancer • Medical professional working in the cancer field • Volunteer with a charity/third sector organisation • Work in cancer research • Work in a university or college and teach about cancer
The next few pages will have questions about what people think about cancer support services. We want to know what issues are important or relevant to ask about when working out if a cancer support service has had an impact on a person. Please remember we are interested in your own opinion based upon your experiences. There are no right or wrong answers. We would like you to rate the following items using a simple star system. You can choose to rate an item from 0 to 5 stars. For example if you rate an item as 0, this means that in	

<table>
<tr><td colspan="2">your opinion this item has no importance or relevance. If you rate an item as 5, this means that in your opinion this item is the most important or relevant.

Whilst some of the items may seem similar or repetitive, please try and rate each possible item.</td></tr>
<tr><td>When looking at whether a cancer support service has had an impact on someone, how relevant do you feel it is to ask about each of these things?

• Anxiety
• Stress
• Post-Traumatic Stress
• Depression
• Mood State
• Worry
• Fear
• Hope
• Coping
• Optimism
• Acceptance
• Distress</td><td>Rate 0 to 5 stars</td></tr>
<tr><td>Thinking about your responses to the previous question, please can you now rate each of these in accordance with what you feel are the most important things to ask about when thinking about the impact of cancer support services. In other words, of these, which are the most and least important?

• Anxiety
• Stress
• Post-Traumatic Stress
• Depression
• Mood State
• Worry
• Fear
• Hope
• Coping
• Optimism
• Acceptance
• Distress</td><td>Rate 0-5 stars</td></tr>
</table>

If you feel we have missed something that you feel is important or relevant please write in the box below	
We would now like you to complete the following questions looking at issues relating to support needs and relationships. We want to know what issues are important or relevant to ask about when working out if a cancer support service has had an impact on a person. These items are rated using the same simple star system as the previous page. As a reminder, you can choose to rate an item from 0 to 5 stars. For example if you rate an item as 0, this means that in your opinion this item has no importance or relevance. If you rate an item as 5, this means that in your opinion this item is the most important or relevant. Whilst some of the items may seem similar or repetitive, please try and rate each possible item. Please remember we are interested in your own opinion based upon your experiences. There are no right or wrong answers.	
When looking at whether a cancer support service has had an impact on someone, how **relevant** do you feel it is to ask about each of these things? • Maintaining relationships • Maintaining friendships • Level of social support • Unmet needs • Loneliness • Isolation • Financial concern • Support following treatment • Spiritual needs	Rate 0 – 5 stars
Thinking about your responses to the previous question, please can you now rate each of these in accordance with what you feel are the most **important** things to ask about when thinking about the impact of cancer support services. In other words, of these, which are the most and least important? • Maintaining relationships • Maintaining friendships • Level of social support	Rate 0-5 stars

• Unmet needs • Loneliness • Isolation • Financial concern • Support following treatment • Spiritual needs	
If you feel we have missed something that you feel is important or relevant please write in the box below	
We would now like you to complete the following questions looking at physical symptoms. We want to know what issues are important or relevant to ask about when working out if a cancer support service has had an impact on a person. These items are rated using the same simple star system as the previous page. As a reminder, you can choose to rate an item from 0 to 5 stars. For example if you rate an item as 0, this means that in your opinion this item has no importance or relevance. If you rate an item as 5, this means that in your opinion this item is the most important or relevant. Whilst some of the items may seem similar or repetitive, please try and rate each possible item. Please remember we are interested in your own opinion based upon your experiences. There are no right or wrong answers.	
When looking at whether a cancer support service has had an impact on someone, how **relevant** do you feel it is to ask about each of these things? • Pain • Discomfort • Symptom progression • Energy levels • Sleep hygiene • Appetite	Rate 0 to 5 stars
Thinking about your responses to the previous question, please can you now rate each of these in accordance with what you feel are the most **important** things to ask about when thinking about the impact of cancer support services. In other words, of these, which are the most and least important?	

• Pain • Discomfort • Symptom progression • Energy levels • Sleep hygiene • Appetite	
If you feel we have missed something that you feel is important or relevant please write in the box below	
We would now like you to think about the practical aspects of using cancer support services. For example, how important it is for services to be quick and easy to access? Again we are interested in the things that are important and relevant to you. There are no right or wrong answers. These items are rated using the same star system as the previous questions. As a reminder, you can choose to rate an item from 0 to 5 stars. For example if you rate an item as 0, this means that in your opinion this item has no importance or relevance. If you rate an item as 5, this means that in your opinion this item is the most important or relevant.	
When looking at the impact of a cancer support service, which of the following things do you feel are **relevant** to measure? • Easy to use • Easy to access • Value for money • Efficiency • Clear instructions • Time involved • Opportunity for feedback • Clear purpose	Rate 0 to 5 stars
When looking at the impact of a cancer support service, how **important** do you feel it is to measure each of these things? • Easy to use • Easy to access • Value for money • Efficiency • Clear instructions • Time involved • Opportunity for feedback • Clear purpose	

If you feel we have missed something that you feel is important or relevant please write in the box below	
Finally, when looking at whether a support service has had an impact on someone, we would like you to tell us how often you think we should be asking about these things. Please select as many options as you like.	Select as many options as you like • Once only (after using a service) • Before and immediately after using a service • Within 6 months of using a service • Within 12 months of using a service • Longer than 12 months • Other: Please select this option to be taken to a free text box
Other time period	
We have now reached the end of the first survey. If you would like to tell us anything else that you think is important or relevant, please feel free to write in the box below. If not, you can click on the arrow at the bottom of the page which will take you to our final thank you page.	
Thank you so much for taking the time to complete the questionnaire. As mentioned at the beginning, there will be a second survey in a few weeks' time. I would really appreciate it if you could complete both surveys, this helps us get a more accurate view of the level of agreement amongst participants. By asking what people who have experienced cancer consider to be the most important and relevant issues to ask about, the information collected in this study will help us to develop a toolkit which will help Tenovus evaluate future services more effectively. If you entered your email address at the beginning the researcher will be in touch soon about the next round of questions. If you are unsure and you would like to re-enter it please do so in the box below. If you have any questions or require more information please get in touch with me Zoe Cooke **(zoe.cooke@uwtsd.ac.uk)** or my supervisor Dr Ceri Phelps **(ceri.phelps@uwtsd.ac.uk)**	

Appendix C – Validated Outcome Measures

Functional Assessment for Cancer Therapy – General (FACT-G)

Below is a list of statements that other people with your illness have said are important**. Please circle or mark one number per line to indicate your response as it applies to the <u>past 7 days</u>.**

	<u>PHYSICAL WELL-BEING</u>	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	<u>SOCIAL/FAMILY WELL-BEING</u>	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4

Survivor Unmet Needs Survey – Short Form (SUNS-SF)

INSTRUCTIONS

We would like to know what unmet needs you have had IN THE LAST MONTH as a result of having cancer now or in the past. An **unmet need** is a need that you have not been able to satisfy.

For each question, place a circle around the number that best describes your level of unmet need IN THE LAST MONTH. Please answer each question, even if you feel there is no way to solve the problem or you do not have any unmet needs.

0	**No unmet need** – This was not a problem for me as a result of having cancer now or in the past.
1	**Low unmet need** – I needed a small amount of help with this problem but was not able to get it.
2	**Moderate unmet need** – I needed a moderate amount of help with this problem but was not able to get it.
3	problem but was not able to get it.
4	**Very high unmet need** – I needed a very high amount of help with this problem but was not able to get it.

For each statement, circle the choice that best describes your level of unmet need.					
	No Unmet Need	**Low Unmet Need**	**Moderate Unmet Need**	**High Unmet Need**	**Very High Unmet Need**
Finding information about complementary or alternative therapies	0	1	2	3	4

If you circled #2, it means that IN THE LAST MONTH, you had a moderate need to know about complementary or alternative therapies but you were not able to get that information or help with

your concerns.

Circle the choice that best describes your level of unmet need.

Knowing how much time I would need away from work	4

If you circled **0**, it means that, IN THE LAST MONTH, knowing how much time you needed away from work was not a problem for you.

We know that your unmet needs may change over time. In this survey, we want to know only about the unmet needs you have had IN THE LAST MONTH.

Please go to the next page to begin the survey.

A. Unmet Information Needs: This part of the survey is about unmet needs that relate to finding information IN THE LAST MONTH

For each statement, circle the choice that best describes your level of unmet need.		***No Unmet Need***	***Low Unmet Need***	***Moderate Unmet Need***	***High Unmet Need***	***Very High Unmet Need***
1.	Finding information about complementary or alternative therapies	0	1	2	3	4
2.	Dealing with fears about cancer spreading	0	1	2	3	4
3.	Dealing with worry about whether the treatment has worked	0	1	2	3	4

B. Unmet Work and Financial Needs: ***This part of the survey is about unmet needs you may have had about your job and finances IN THE LAST MONTH***

For each statement, circle the choice that best describes your level of unmet need.		***No Unmet Need***	***Low Unmet Need***	***Moderate Unmet Need***	***High Unmet Need***	***Very High Unmet Need***
4.	Worry about earning money	0	1	2	3	4
5.	Having to take a pension or disability allowance	0	1	2	3	4
6.	Paying household bills or other payments	0	1	2	3	4
7.	Finding what type of financial assistance is available and how to obtain it	0	1	2	3	4
8.	Finding car parking that I can afford at the hospital or clinic	0	1	2	3	4
9.	Understanding what is covered by my medical insurance or benefits	0	1	2	3	4
10.	Knowing how much time I would need away from work	0	1	2	3	4
11.	Doing work around the house (cooking, cleaning, home repairs, etc.)	0	1	2	3	4

C. Unmet Needs for Access and Continuity of Care: ***This part of the survey is about unmet needs that relate to medical care IN THE LAST MONTH***

For each statement, circle the choice that best describes your level of unmet need.		*No Unmet Need*	*Low Unmet Need*	*Moderate Unmet Need*	*High Unmet Need*	*Very High Unmet Need*
12.	Having access to cancer services close to my home	0	1	2	3	4
13.	Getting appointments with specialists quickly enough (oncologist, surgeon, etc.)	0	1	2	3	4
14.	Getting test results quickly enough	0	1	2	3	4
15.	Having access to care from other health specialists (dieticians, physiotherapists, occupational therapists)	0	1	2	3	4
16.	Making sure I had enough time to ask my doctor or nurse questions	0	1	2	3	4
17.	Getting the health care team to attend promptly to my physical needs	0	1	2	3	4

D. Unmet Coping, Sharing and Emotional Needs: This part of the survey is about unmet needs that relate to your relationships with others and your emotional health IN THE LAST MONTH

For each statement, circle the choice that best describes your level of unmet need		*No Unmet Need*	*Low Unmet Need*	*Moderate Unmet Need*	*High Unmet Need*	*Very High Unmet Need*
18.	Telling others how I was feeling emotionally	0	1	2	3	4
19.	Finding someone to talk to who understands and has been through a similar experience	0	1	2	3	4

20.	Dealing with people who expect me to be “back to normal”	0	1	2	3	4
21.	Dealing with people accepting that having cancer has changed me as a person	0	1	2	3	4

	For each statement, circle the choice that best describes your level of unmet need.	***No Unmet Need***	***Low Unmet Need***	***Moderate Unmet Need***	***High Unmet Need***	***Very High Unmet Need***
22.	Dealing with reduced support from others when treatment has ended	0	1	2	3	4
23.	Dealing with feeling depressed	0	1	2	3	4
24.	Dealing with feeling tired	0	1	2	3	4
25.	Dealing with feeling stressed	0	1	2	3	4
26.	Dealing with feeling lonely	0	1	2	3	4
27.	Dealing with not being able to feel ‘normal’	0	1	2	3	4
28.	Trying to stay positive	0	1	2	3	4
29.	Coping with having a bad memory or lack of focus	0	1	2	3	4
30.	Dealing with changes in how my body appears	0	1	2	3	4

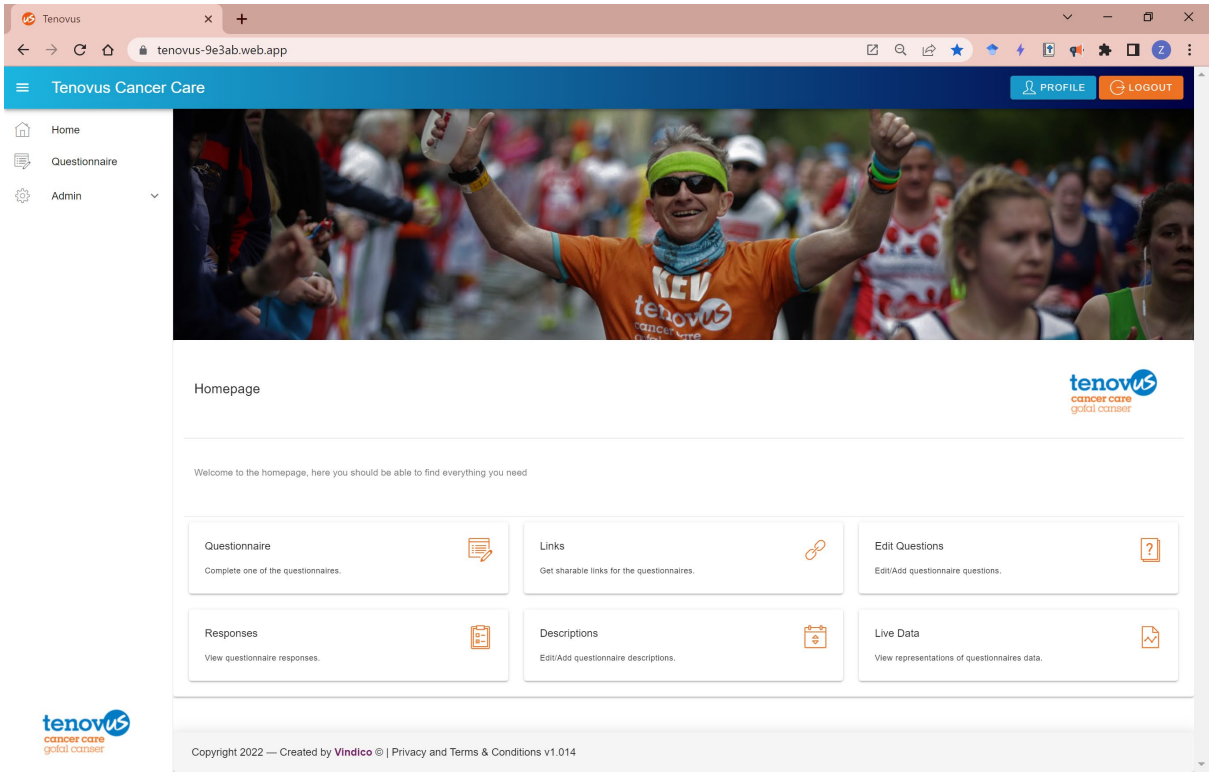
Cancer Loneliness Scale (CLS)

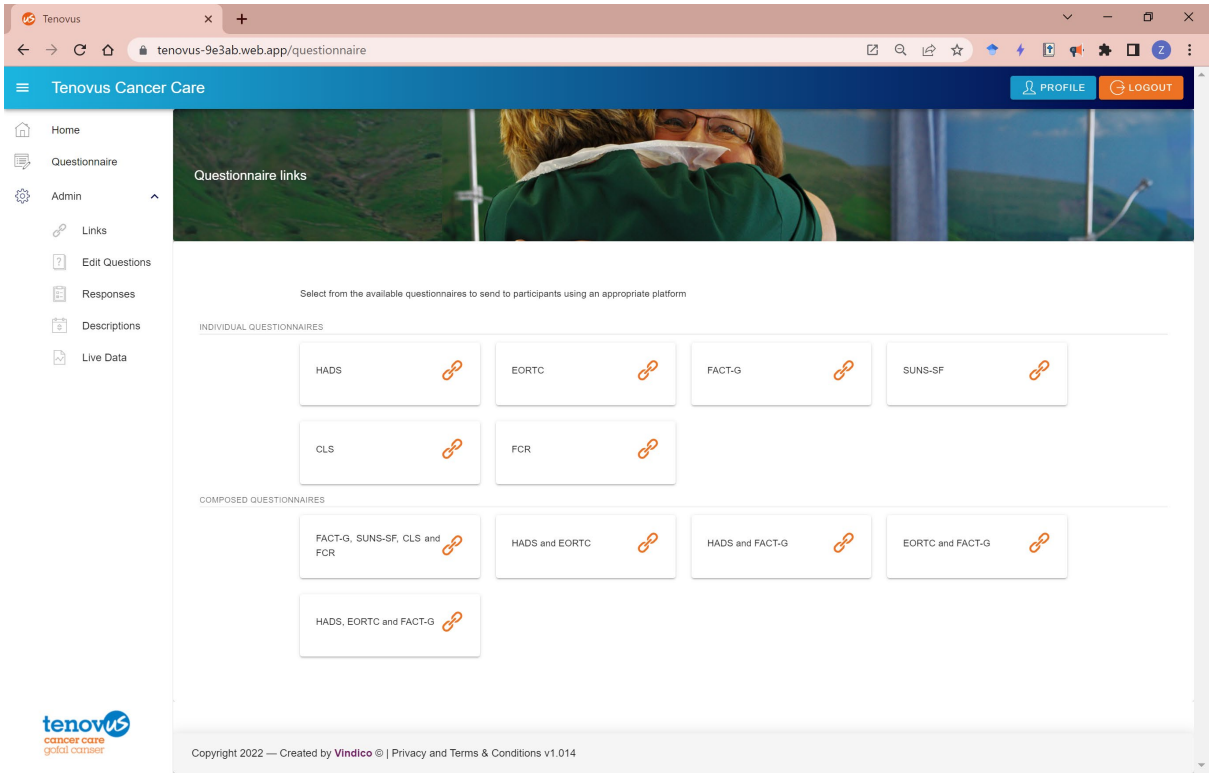
The following statements describe how people sometimes feel after being diagnosed with cancer. For each statement, please indicate how often you have felt that way by selecting an option that best represents your feelings.

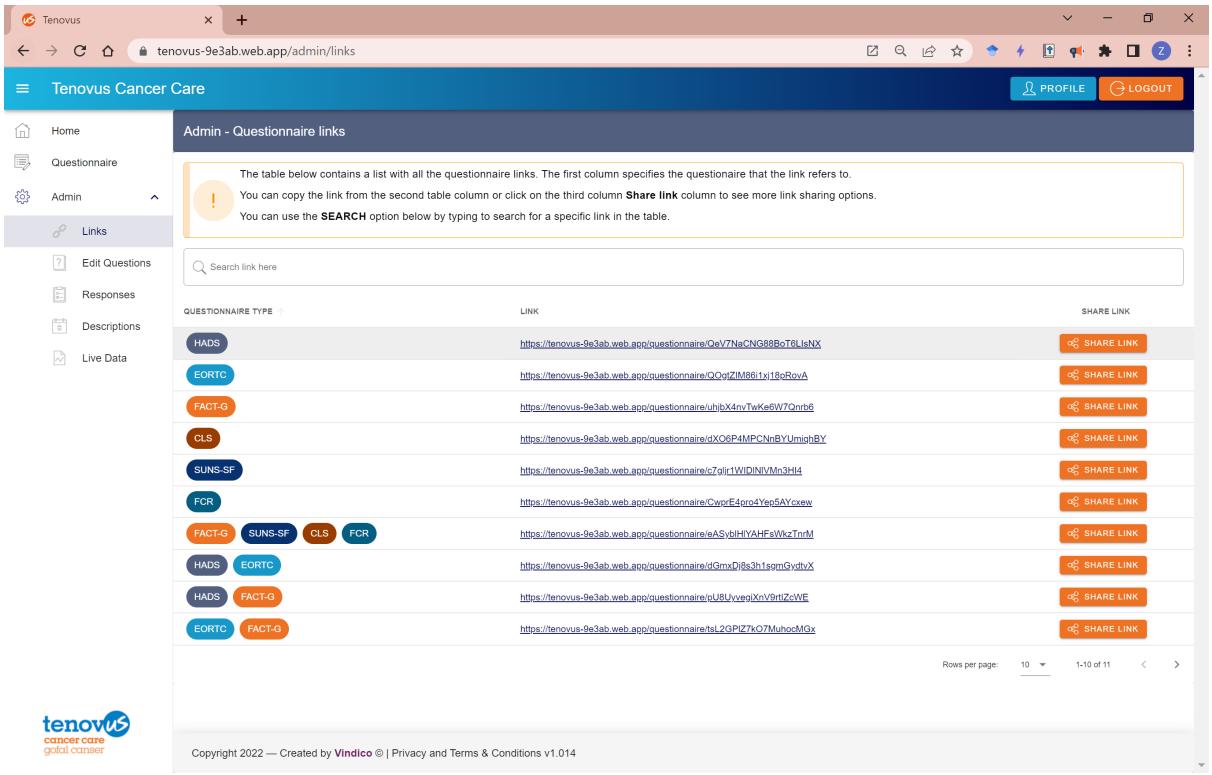
1. Since your cancer diagnosis, how often have you felt misunderstood even by your closest friends and family members?				
Never 0	Rarely 1	Sometimes 2	Often 3	Always 4
2. How often do you feel that others cannot provide the support you need to deal with your cancer?				
Never 0	Rarely 1	Sometimes 2	Often 3	Always 4
3. Since your cancer diagnosis, how often have you felt that you don't have a lot in common with the people around you?				
Never 0	Rarely 1	Sometimes 2	Often 3	Always 4
4. How often do you feel that you cannot share personal thoughts about cancer with anyone?				
Never 0	Rarely 1	Sometimes 2	Often 3	Always 4
5. Since your cancer diagnosis, how often have you felt that you were not needed by others?				
Never 0	Rarely 1	Sometimes 2	Often 3	Always 4
6. Since your cancer diagnosis, how often have you experienced a general sense of emptiness				
Never 0	Rarely 1	Sometimes 2	Often 3	Always 4
7. How often does your cancer diagnosis make you feel isolated from others?				
Never 0	Rarely 1	Sometimes 2	Often 3	Always 4

Appendix D – Tenovus: Psychosocial Outcomes Toolkit (T:POT) interface

URL to access the interface: https://tenovus-9e3ab.web.app/



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You can copy the link from the second table column or click on the third column Share link column to see more link sharing options.
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EORTC https://tenovus-9e3ab.web.app/questionnaire/QOqtZIM86i1xj18qRovA SHARE LINK
FACT-G https://tenovus-9e3ab.web.app/questionnaire/uhjbX4nvTwKe6W7Qnrb6 SHARE LINK
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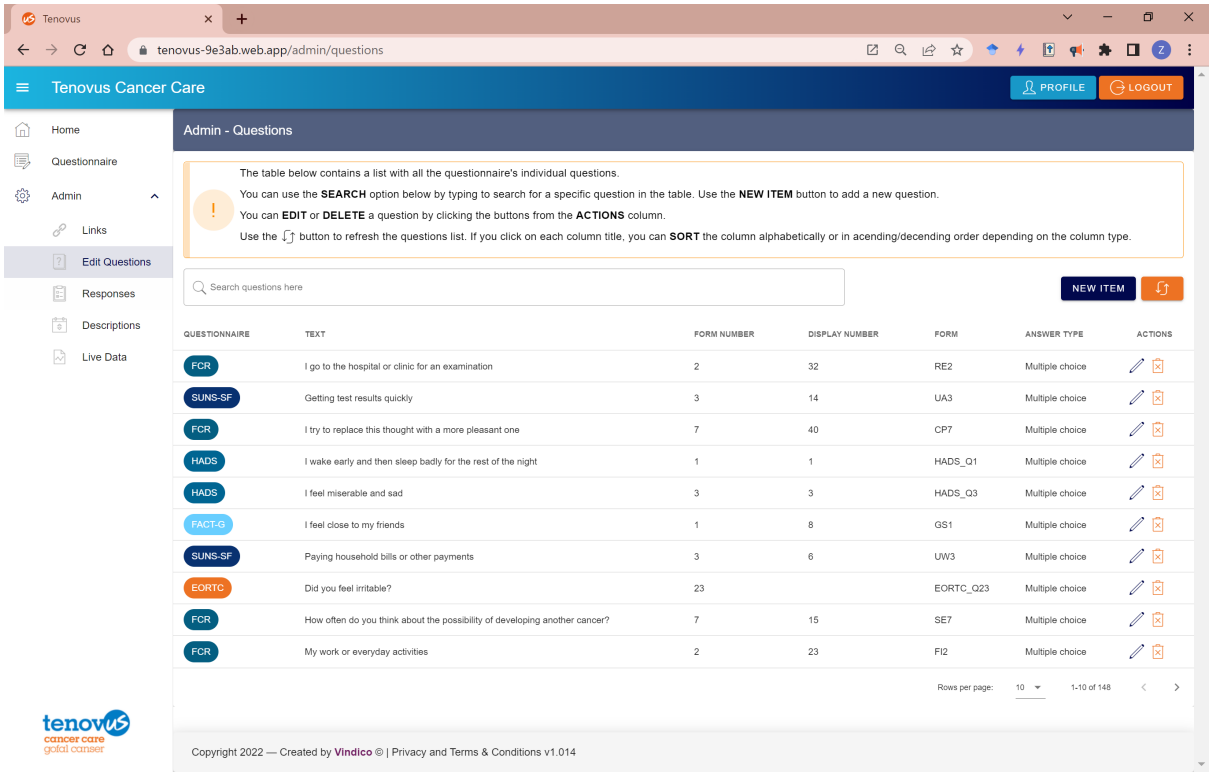
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You can use the SEARCH option below by typing to search for a specific question in the table. Use the NEW ITEM button to add a new question.
You can EDIT or DELETE a question by clicking the buttons from the ACTIONS column.
Use the button to refresh the questions list. If you click on each column title, you can SORT the column alphabetically or in acending/decending order depending on the column type.
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DISPLAY NUMBER
FORM
ANSWER TYPE
ACTIONS
FCR I go to the hospital or clinic for an examination 2 32 RE2 Multiple choice
SUNS-SF Getting test results quickly 3 14 UA3 Multiple choice
FCR I try to replace this thought with a more pleasant one 7 40 CP7 Multiple choice
HADS I wake early and then sleep badly for the rest of the night 1 1 HADS_Q1 Multiple choice
HADS I feel miserable and sad 3 3 HADS_Q3 Multiple choice
FACT-G I feel close to my friends 1 8 GS1 Multiple choice
SUNS-SF Paying household bills or other payments 3 6 UW3 Multiple choice
EORTC Did you feel irritable? 23 EORTC_Q23 Multiple choice
FCR How often do you think about the possibility of developing another cancer? 7 15 SE7 Multiple choice
FCR My work or everyday activities 2 23 FI2 Multiple choice
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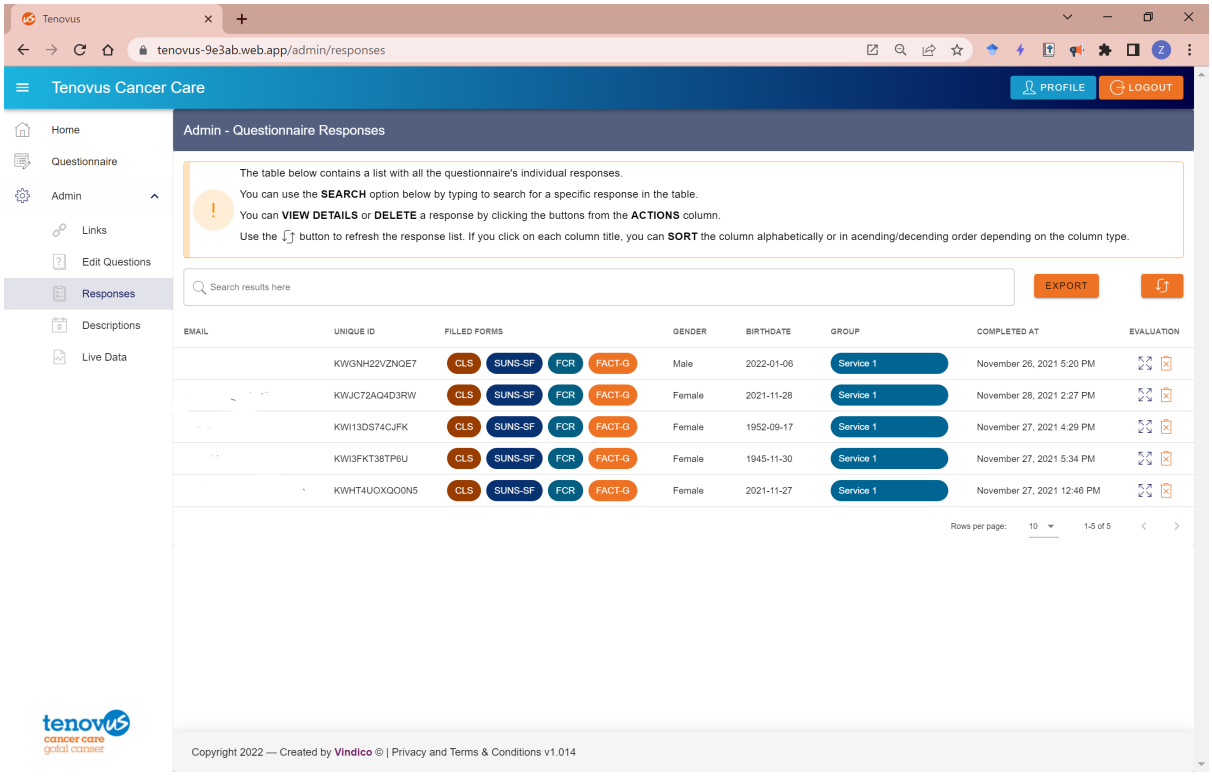
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You can use the SEARCH option below by typing to search for a specific response in the table.
You can VIEW DETAILS or DELETE a response by clicking the buttons from the ACTIONS column.
Use the button to refresh the response list. If you click on each column title, you can SORT the column alphabetically or in acending/decending order depending on the column type.
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KWI13DS74CJFK CLS SUNS-SF FCR FACT-G Female 1952-09-17 Service 1 November 27, 2021 4:29 PM
KWI3FKT38TP6U CLS SUNS-SF FCR FACT-G Female 1945-11-30 Service 1 November 27, 2021 5:34 PM
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1-5 of 5
tenovus cancer care gofal canser
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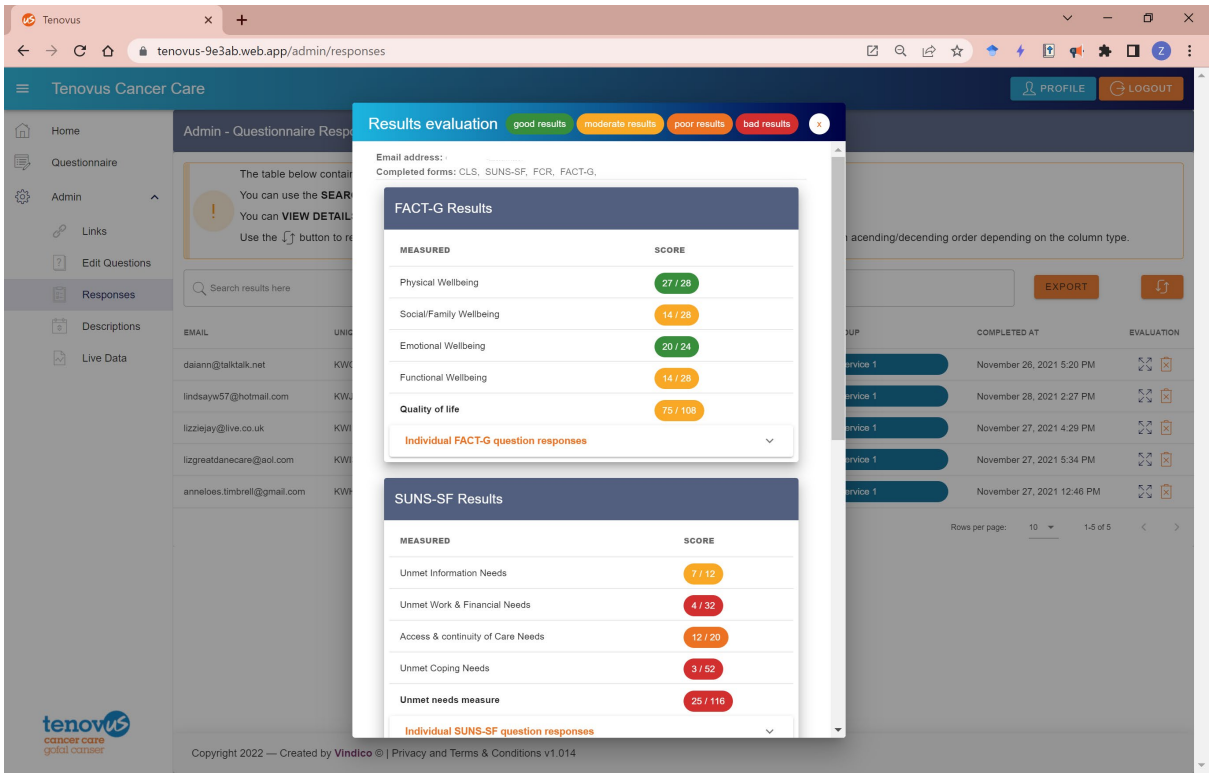
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Responses
Descriptions
Live Data
Results evaluation
good results
moderate results
poor results
bad results
Email address:
Completed forms: CLS, SUNS-SF, FCR, FACT-G,
FACT-G Results
MEASURED
SCORE
Physical Wellbeing 27 / 28
Social/Family Wellbeing 14 / 28
Emotional Wellbeing 20 / 24
Functional Wellbeing 14 / 28
Quality of life 75 / 108
Individual FACT-G question responses
SUNS-SF Results
MEASURED
SCORE
Unmet Information Needs 7 / 12
Unmet Work & Financial Needs 4 / 32
Access & continuity of Care Needs 12 / 20
Unmet Coping Needs 3 / 52
Unmet needs measure 25 / 116
Individual SUNS-SF question responses
EXPORT
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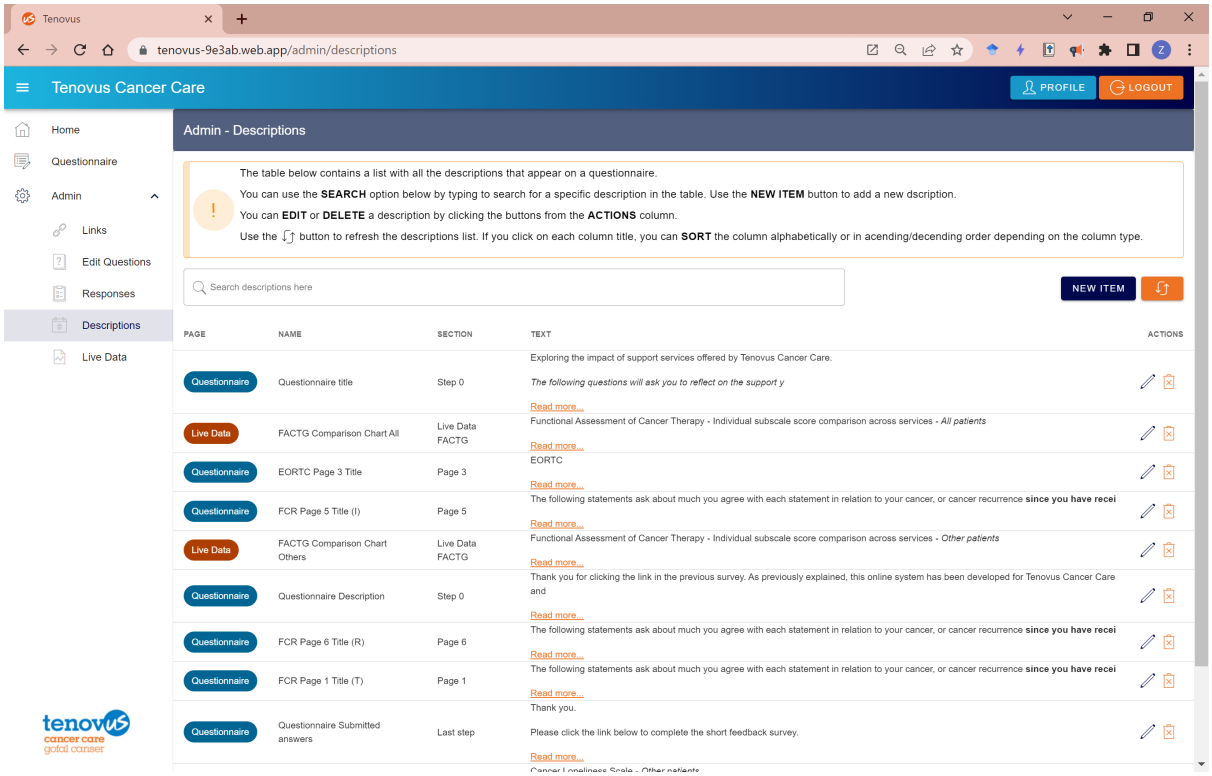
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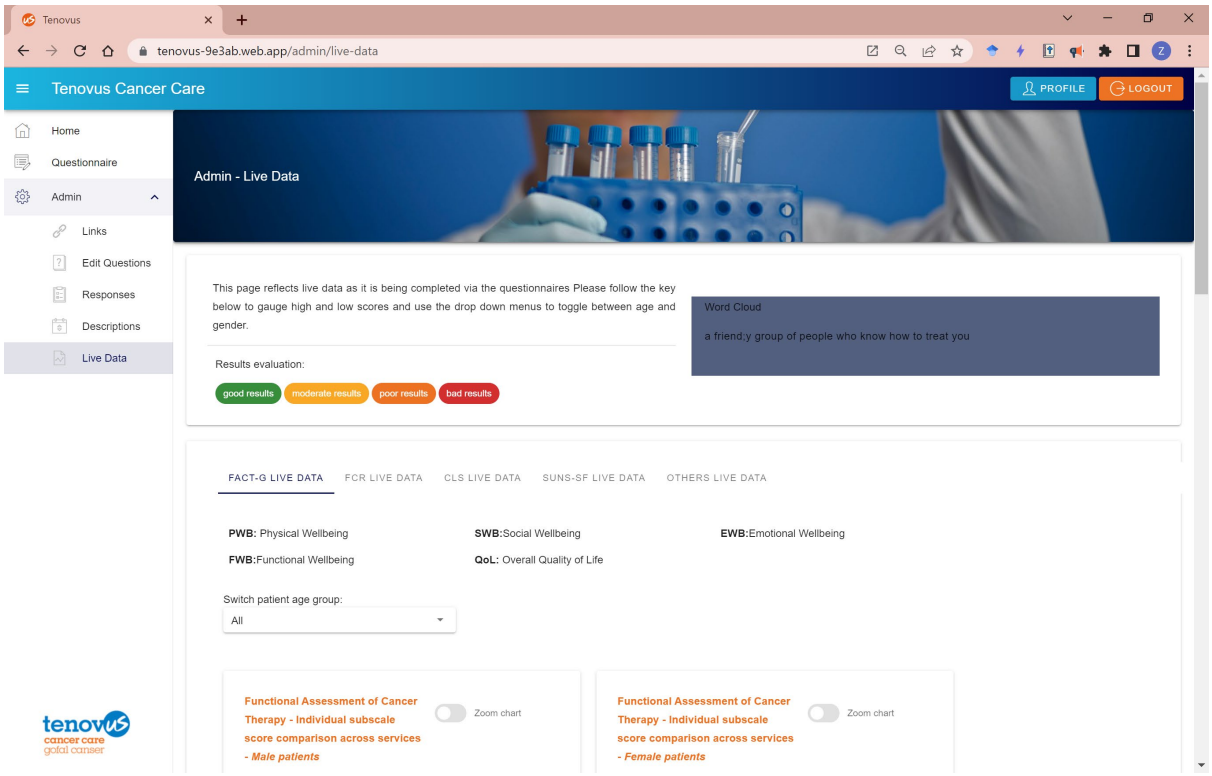
Admin - Descriptions
The table below contains a list with all the descriptions that appear on a questionnaire.
You can use the SEARCH option below by typing to search for a specific description in the table. Use the NEW ITEM button to add a new dscription.
You can EDIT or DELETE a description by clicking the buttons from the ACTIONS column.
Use the button to refresh the descriptions list. If you click on each column title, you can SORT the column alphabetically or in acending/decending order depending on the column type.
Search descriptions here
NEW ITEM
PAGE
NAME
SECTION
TEXT
ACTIONS
Questionnaire
Questionnaire title
Step 0
Exploring the impact of support services offered by Tenovus Cancer Care.
The following questions will ask you to reflect on the support y
Read more...
Live Data
FACTG Comparison Chart All
Live Data FACTG
Functional Assessment of Cancer Therapy - Individual subscale score comparison across services - All patients
Read more...
Questionnaire
EORTC Page 3 Title
Page 3
EORTC
Read more...
Questionnaire
FCR Page 5 Title (I)
Page 5
The following statements ask about much you agree with each statement in relation to your cancer, or cancer recurrence since you have recei
Read more...
Live Data
FACTG Comparison Chart Others
Live Data FACTG
Functional Assessment of Cancer Therapy - Individual subscale score comparison across services - Other patients
Read more...
Questionnaire
Questionnaire Description
Step 0
Thank you for clicking the link in the previous survey. As previously explained, this online system has been developed for Tenovus Cancer Care and
Read more...
Questionnaire
FCR Page 6 Title (R)
Page 6
The following statements ask about much you agree with each statement in relation to your cancer, or cancer recurrence since you have recei
Read more...
Questionnaire
FCR Page 1 Title (T)
Page 1
The following statements ask about much you agree with each statement in relation to your cancer, or cancer recurrence since you have recei
Read more...
Questionnaire
Questionnaire Submitted answers
Last step
Thank you.
Please click the link below to complete the short feedback survey.
Read more...
tenovus cancer care gofal canser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Tenovus Cancer Care
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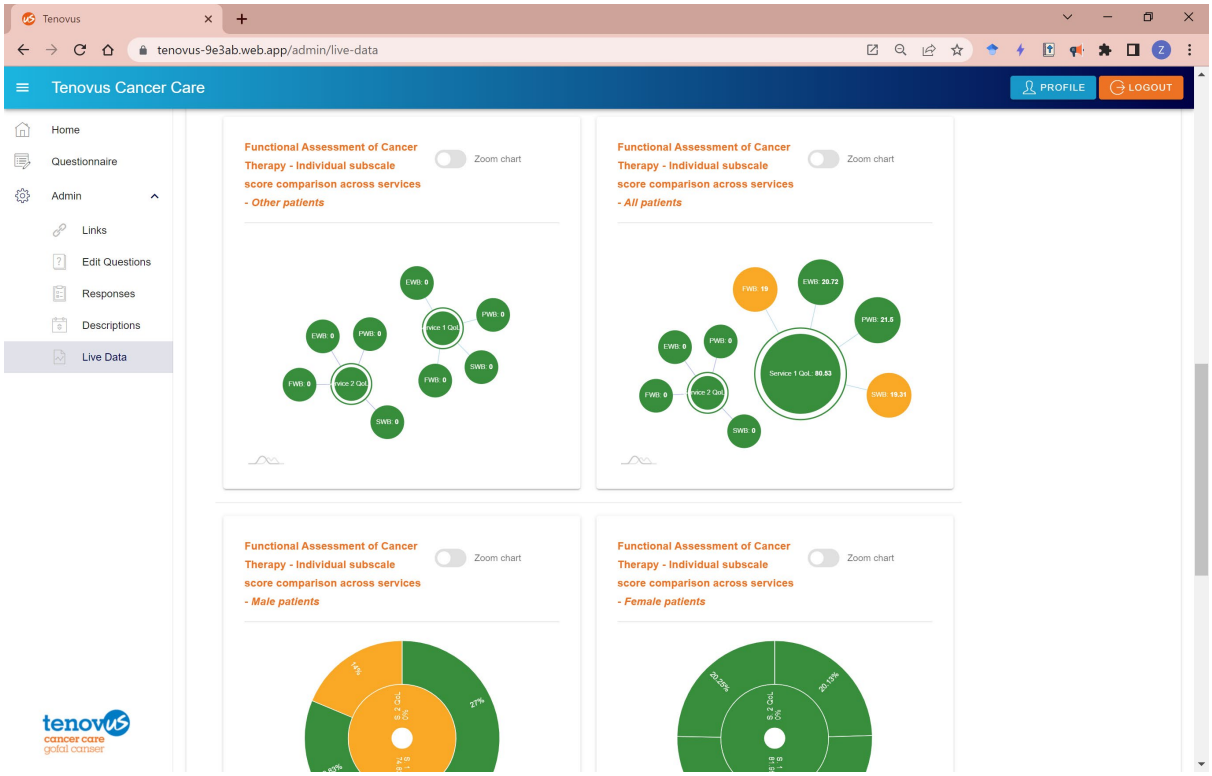
Questionnaire
Admin
Links
Edit Questions
Responses
Descriptions
Live Data
Admin - Live Data
This page reflects live data as it is being completed via the questionnaires Please follow the key below to gauge high and low scores and use the drop down menus to toggle between age and gender.
Word Cloud
a friend;y group of people who know how to treat you
Results evaluation:
good results
moderate results
poor results
bad results
FACT-G LIVE DATA
FCR LIVE DATA
CLS LIVE DATA
SUNS-SF LIVE DATA
OTHERS LIVE DATA
PWB: Physical Wellbeing
SWB:Social Wellbeing
EWB:Emotional Wellbeing
FWB:Functional Wellbeing
QoL: Overall Quality of Life
Switch patient age group:
All
Functional Assessment of Cancer Therapy - Individual subscale score comparison across services - Male patients
Zoom chart
Functional Assessment of Cancer Therapy - Individual subscale score comparison across services - Female patients
Zoom chart
tenovus cancer care gofal canser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Responses
Descriptions
Live Data
Functional Assessment of Cancer Therapy - Individual subscale score comparison across services - Other patients
Zoom chart
Functional Assessment of Cancer Therapy - Individual subscale score comparison across services - All patients
Zoom chart
Functional Assessment of Cancer Therapy - Individual subscale score comparison across services - Male patients
Zoom chart
Functional Assessment of Cancer Therapy - Individual subscale score comparison across services - Female patients
Zoom chart
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Appendix E – User experience evaluation study materials

UEQ

Please make your evaluation now.

For the assessment of the product, please fill out the following questionnaire. The questionnaire consists of pairs of contrasting attributes that may apply to the product. The circles between the attributes represent gradations between the opposites. You can express your agreement with the attributes by ticking the circle that most closely reflects your impression.

Example:

attractive	○	⊗	○	○	○	○	○	unattractive

This response would mean that you rate the application as more attractive than unattractive.

Please decide spontaneously. Don't think too long about your decision to make sure that you convey your original impression.

Sometimes you may not be completely sure about your agreement with a particular attribute or you may find that the attribute does not apply completely to the particular product. Nevertheless, please tick a circle in every line.

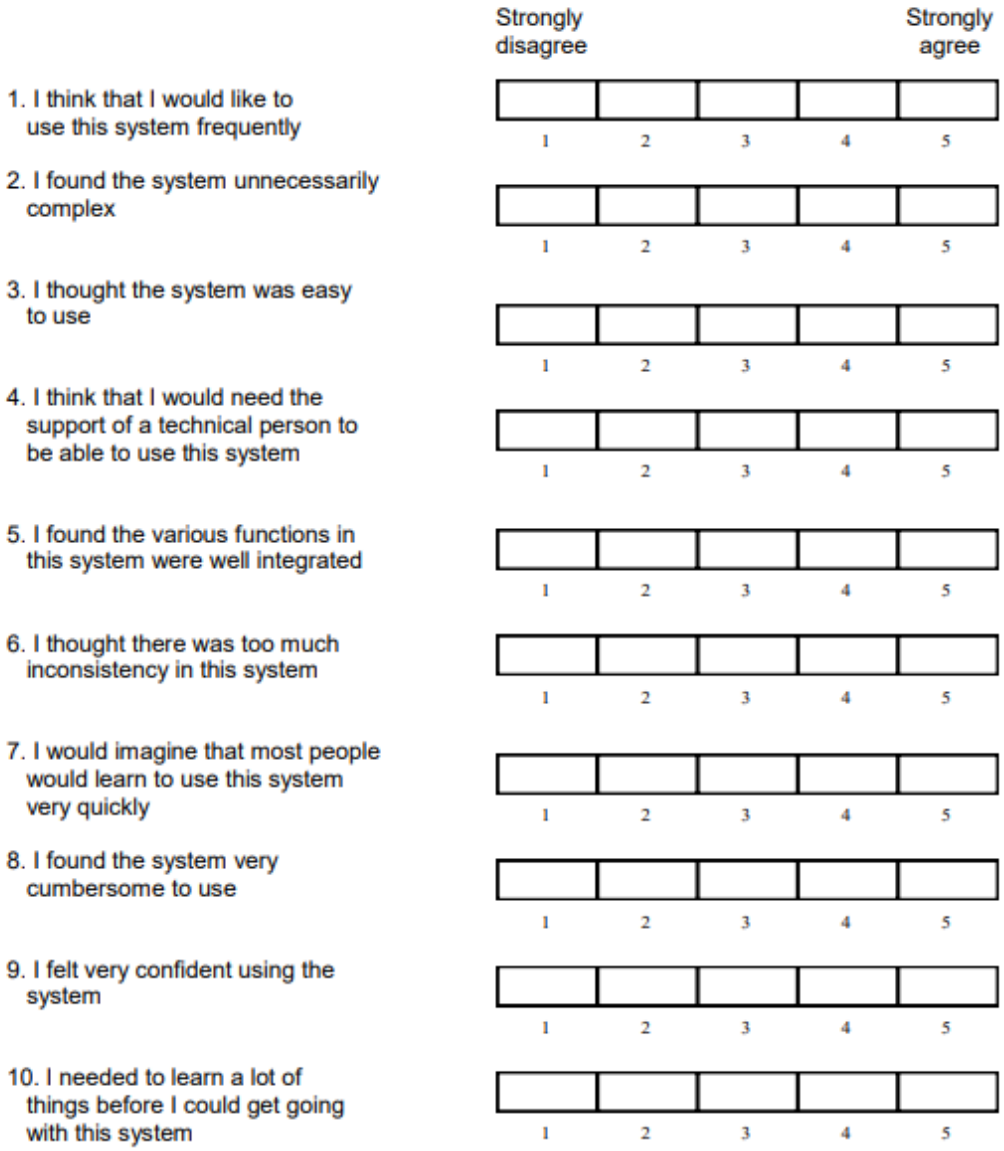
It is your personal opinion that counts. Please remember: there is no wrong or right answer!

Please assess the product now by ticking one circle per line.

	1	2	3	4	5	6	7		
annoying	○	○	○	○	○	○	○	enjoyable	1
not understandable	○	○	○	○	○	○	○	understandable	2
creative	○	○	○	○	○	○	○	dull	3
easy to learn	○	○	○	○	○	○	○	difficult to learn	4
valuable	○	○	○	○	○	○	○	inferior	5
boring	○	○	○	○	○	○	○	exciting	6
not interesting	○	○	○	○	○	○	○	interesting	7
unpredictable	○	○	○	○	○	○	○	predictable	8
fast	○	○	○	○	○	○	○	slow	9
inventive	○	○	○	○	○	○	○	conventional	10
obstructive	○	○	○	○	○	○	○	supportive	11
good	○	○	○	○	○	○	○	bad	12
complicated	○	○	○	○	○	○	○	easy	13
unlikable	○	○	○	○	○	○	○	pleasing	14
usual	○	○	○	○	○	○	○	leading edge	15
unpleasant	○	○	○	○	○	○	○	pleasant	16
secure	○	○	○	○	○	○	○	not secure	17
motivating	○	○	○	○	○	○	○	demotivating	18
meets expectations	○	○	○	○	○	○	○	does not meet expectations	19
inefficient	○	○	○	○	○	○	○	efficient	20
clear	○	○	○	○	○	○	○	confusing	21
impractical	○	○	○	○	○	○	○	practical	22
organized	○	○	○	○	○	○	○	cluttered	23
attractive	○	○	○	○	○	○	○	unattractive	24
friendly	○	○	○	○	○	○	○	unfriendly	25
conservative	○	○	○	○	○	○	○	innovative	26

SUS

System Usability Scale

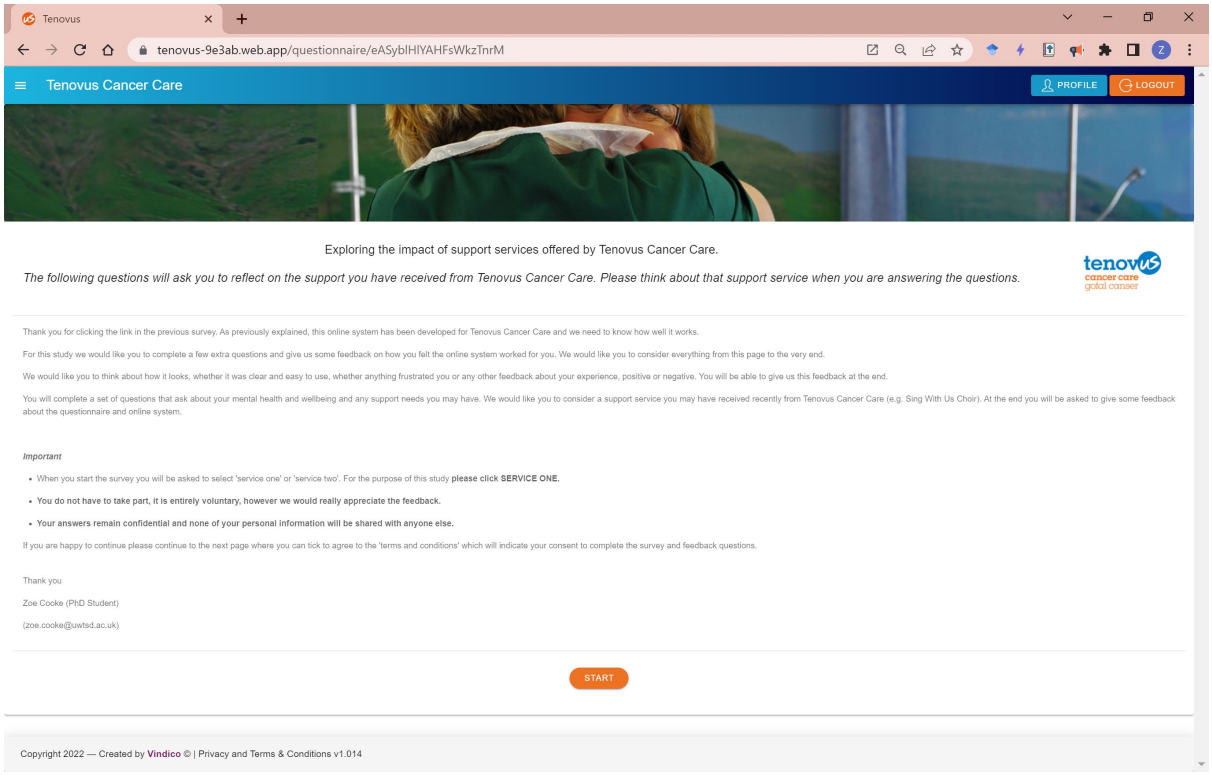


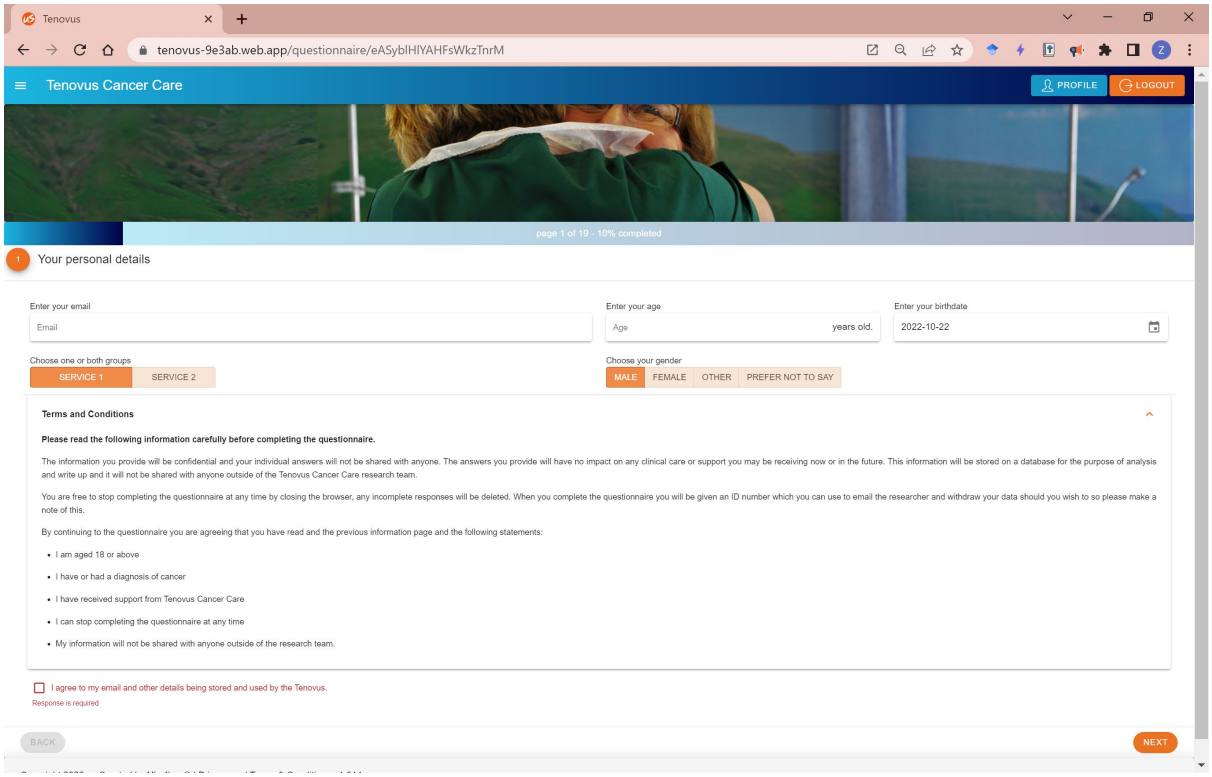
Study information sheet for UX study 2

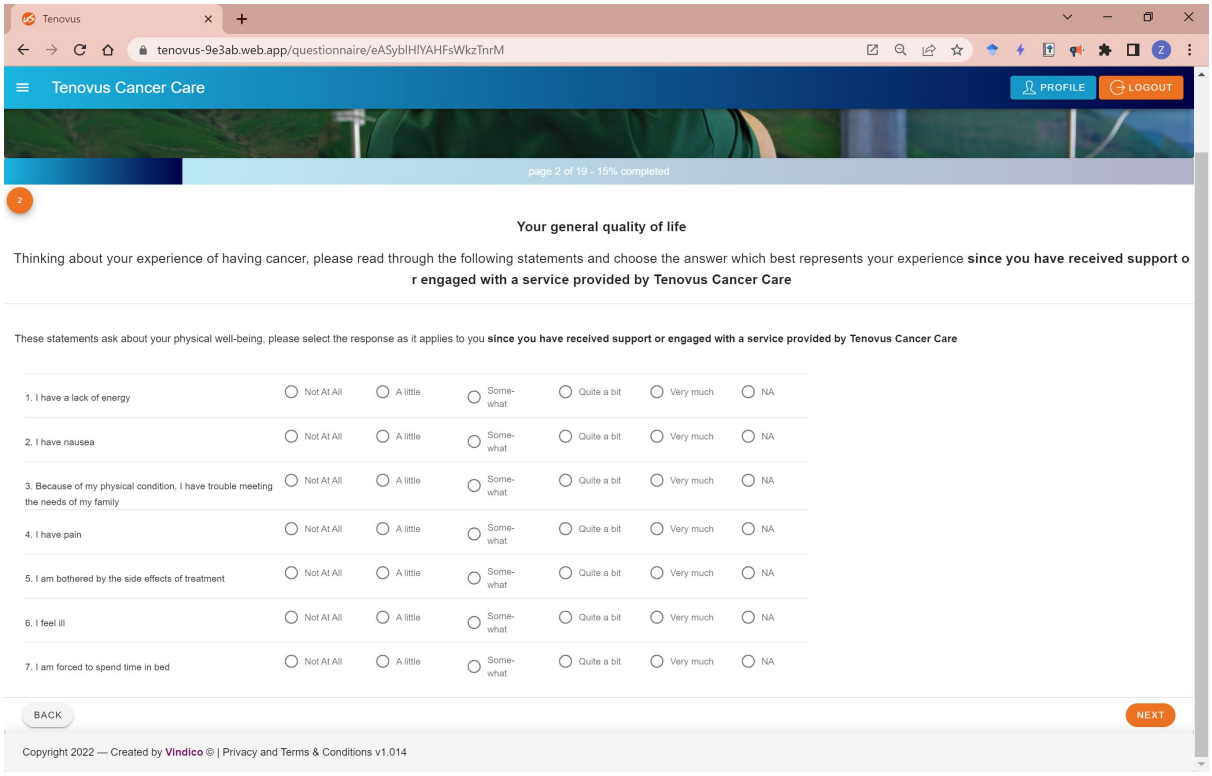
We are hoping the system you have just used will be used by Tenovus Cancer Care in the future. Please respond to the final set of questions below and tell us how you found using it as someone who uses Tenovus services.

If you have any questions or further comments, please email Zoe (zoe.cooke@uwstd.ac.uk)

Appendix F – Study 3 materials






Tenovus
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Tenovus Cancer Care
PROFILE
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page 2 of 19 - 15% completed
2
Your general quality of life
Thinking about your experience of having cancer, please read through the following statements and choose the answer which best represents your experience since you have received support o r engaged with a service provided by Tenovus Cancer Care
These statements ask about your physical well-being, please select the response as it applies to you since you have received support or engaged with a service provided by Tenovus Cancer Care
1. I have a lack of energy
2. I have nausea
3. Because of my physical condition, I have trouble meeting the needs of my family
4. I have pain
5. I am bothered by the side effects of treatment
6. I feel ill
7. I am forced to spend time in bed
Not At All
A little
Some-what
Quite a bit
Very much
NA
BACK
NEXT
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Study information sheet

Returning to the Sing With Us Choir and beyond.

University of Wales Trinity Saint David (UWTSD) are helping Tenovus Cancer Care to evaluate their services for people affected by cancer.

This study is looking for people with or affected by cancer who have been a member of a Tenovus Cancer Care 'Sing With Us' Choir. We would like to find out a bit about how you found the virtual choirs over the last 18 months, how you are feeling about returning to choir practice, and if you are planning to return to in-person practice.

We would like you to complete a short online survey that asks about your views of the Tenovus Sing With Us Choirs. This survey will take around 5 minutes of your time and it is entirely up to you to decide whether or not you would like to complete it. The data from the survey will help Tenovus continue to offer appropriate support to people affected by cancer.

If you have a current or previous personal diagnosis of cancer we will also ask you to consider completing some further questionnaires as an additional part of this study. This is completely optional and we will tell you more about this at the end of the first survey so you do not need to decide now.

Your answers to the choir survey are completely anonymous, we are not asking you for any information that would identify you. The answers you provide will not be linked back to you when analysed. Any published data will be anonymised in accordance with the General Data Protection Regulation (GDPR, 2016) and Data Protection Act (2018).

Thank you for considering taking part in this survey. If you would like to proceed, please click the arrow to complete the consent form.

Contact Details

If there is anything that is not clear or you would simply like more information please contact Zoe Cooke (PhD Student) or Dr Ceri Phelps (Supervisor).

You can also contact the Tenovus Cancer Care Support line (Mon-Fri 9am-5pm/ Weekends 10am-1pm).

Zoe Cooke (PhD Student)
Zoe.cooke@uwtsd.ac.uk

Dr Ceri Phelps
ceri.phelps@uwtsd.ac.uk

Tenovus Cancer Care Support Line
0808 808 1010 (FREE)

As you have indicated that you have a current or previous cancer diagnosis, we are hoping that you may be willing to answer a few more questions which will take no more than 20 minutes of your time.

As part of a PhD study at UWTSD we have been developing an online system where Tenovus Cancer Care can explore the impact that their services have had on an individual with cancer, and what the best questions are to ask. We have developed an online survey system to collect important data about Tenovus services, but we now need to find out whether those using Tenovus services find it is easy to use, relevant and appropriate. We would therefore like you to help us test out that system by using it to answer further questions in relation to your use of the Tenovus Sing With Us Choir.

Please click this link to go to the second survey. Once you have clicked this link, a new browser window will open. If you do not wish to take part or change your mind, you can close the browser at any time.

Once you start the next survey, your information will no longer be anonymous as we ask for your email address, but it will remain strictly confidential. Thank you for considering taking part in this next step, your experience is vital to us knowing whether we have developed something that will be useful to Tenovus Cancer Care and to people affected by cancer, however you do not have to take part.

If you have any questions or require further support, please feel free to get in touch using the details below.

Zoe Cooke (PhD Student) Zoe.cooke@uwtsd.ac.uk

Dr Ceri Phelps (Supervisor) ceri.phelps@uwtsd.ac.uk

You can also contact the Tenovus Cancer Care Support line (Mon-Fri 9am-5pm/ Weekends 10am-1pm).
Tenovus Cancer Care Support Line 0808 808 1010 (FREE)

Thinking about your experience of having cancer, please read through the following statements and choose the answer which best represents your experience **since you have received support or engaged with a service provide d by Tenovus Cancer Care**

These statements ask about your physical well-being, please select the response as it applies to you **since you have received support or engaged with a service provided by Tenovus Cancer Care**

	Not at all	A little bit	Some-what	Quite a bit	Very much
1. I have nausea					
2. Because of my physical condition, I have trouble meeting the needs of my family					
3. I have pain					
4. I am bothered by the side effects of treatment					
5. I feel ill					
6. I am forced to spend time in bed					
7. I feel close to my friends					
8. I get emotional support from my family					
9. I get support from my friends					
10. I feel close to my partner (or the person who is my main support)					
11. I am satisfied with my sex life (optional answer)					

12. I feel sad					
13. I feel nervous					
14. I worry about dying					
15. I worry that my condition will get worse					
16. I am able to work (include work at home)					
17. My work (include work at home) is fulfilling					
18. I am able to enjoy life					
19. I am sleeping well					
20. I am enjoying the things I usually do for fun					
21. I am content with the quality of my life right now					

Unmet Information Needs

These statements reflect unmet needs in relation to finding information about your cancer **since you have received support or engaged with a service provid ed by Tenovus Cancer Care**

Your cancer-related support needs

The following questions ask about your support needs **since you have received support or engaged with a service provided by Tenovus Cancer Care**. An unmet need is a need that you have not been able to satisfy. For each question, please think about the level of unmet need you have experienced as a result of having cancer **since you have received support or engaged with a service provided by Tenovus Cancer Care**. If any of these statements do not apply to you, please select N/A.

- ***No unmet need**= This was not a problem for me as a result of having cancer now or in the past*
- ***Low unmet need**= I needed a small amount of help with this problem but was not able to get it*
- ***Moderate unmet need**= I needed a moderate amount of help with this problem but was not able to get it*
- ***High unmet need**= I needed a high amount of help with this problem but was not able to get it*
- ***Very high unmet need**= I needed a very high amount of help with this problem but was not able to get*

	No unmet need	Low unmet need	Moderate unmet need	High unmet need	Very high unmet need
Finding information about complementary or alternative therapies	0	1	2	3	4
Dealing with fears about cancer spreading	0	1	2	3	4
Dealing with worry about whether the treatment has worked	0	1	2	3	4
Worry about earning money	0	1	2	3	4

Having to take a pension or disability allowance	0	1	2	3	4
Paying household bills or other payments	0	1	2	3	4
Finding what type of financial assistance is available and how to obtain it	0	1	2	3	4
Finding car parking that I can afford at the hospital or clinic	0	1	2	3	4
Understanding what is covered by my medical insurance or benefits	0	1	2	3	4
Knowing how much time I would need away from work	0	1	2	3	4
Doing work around the house (cooking, cleaning, home repairs, etc.)	0	1	2	3	4
Having access to cancer services close to my home	0	1	2	3	4
Getting appointments with specialists quickly enough (Oncologist, Surgeon, etc.)	0	1	2	3	4
Getting test results quickly	0	1	2	3	4
Having access to care from other health specialists (Dieticians, Physiotherapists, Occupational therapists, etc.)	0	1	2	3	4
Getting the health care team to attend promptly to my physical needs	0	1	2	3	4
Telling others how I was feeling emotionally	0	1	2	3	4
Finding someone to talk to who understands and has been through a similar experience	0	1	2	3	4

Dealing with people who expect me to be "back to normal”	0	1	2	3	4
Dealing with people accepting that having cancer has changed me as a person	0	1	2	3	4
Dealing with reduced support from others when treatment has ended	0	1	2	3	4
Dealing with feeling depressed	0	1	2	3	4
Dealing with feeling tired	0	1	2	3	4
Dealing with feeling stressed	0	1	2	3	4
Dealing with feeling lonely	0	1	2	3	4
Dealing with not being able to feel 'normal’	0	1	2	3	4
Trying to stay positive	0	1	2	3	4
Coping with having a bad memory or lack of focus	0	1	2	3	4
Dealing with changes in how my body appears	0	1	2	3	4

Cancer Loneliness Scale

Cancer Loneliness Scale

The following statements describe how people sometimes feel after being diagnosed with cancer. For each statement, please indicate how often you have felt that way by selecting an option that best represents your feelings **since you have received support or engaged with a service provided by Tenovus Cancer Care**. If the statement is not applicable to you please select N/A.

1. Since your cancer diagnosis, how often have you felt misunderstood even by your closest friends and family members?				
Never 0	Rarely 1	Sometimes 2	Often 3	Always 4

2. How often do you feel that others cannot provide the support you need to deal with your cancer?				
Never 0	Rarely 1	Sometimes 2	Often 3	Always 4
3. Since your cancer diagnosis, how often have you felt that you don't have a lot in common with the people around you?				
Never 0	Rarely 1	Sometimes 2	Often 3	Always 4
4. How often do you feel that you cannot share personal thoughts about cancer with anyone?				
Never 0	Rarely 1	Sometimes 2	Often 3	Always 4
5. Since your cancer diagnosis, how often have you felt that you were not needed by others?				
Never 0	Rarely 1	Sometimes 2	Often 3	Always 4
6. Since your cancer diagnosis, how often have you experienced a general sense of emptiness				
Never 0	Rarely 1	Sometimes 2	Often 3	Always 4
7. How often does your cancer diagnosis make you feel isolated from others?				
Never 0	Rarely 1	Sometimes 2	Often 3	Always 4

Fear of Cancer Recurrence

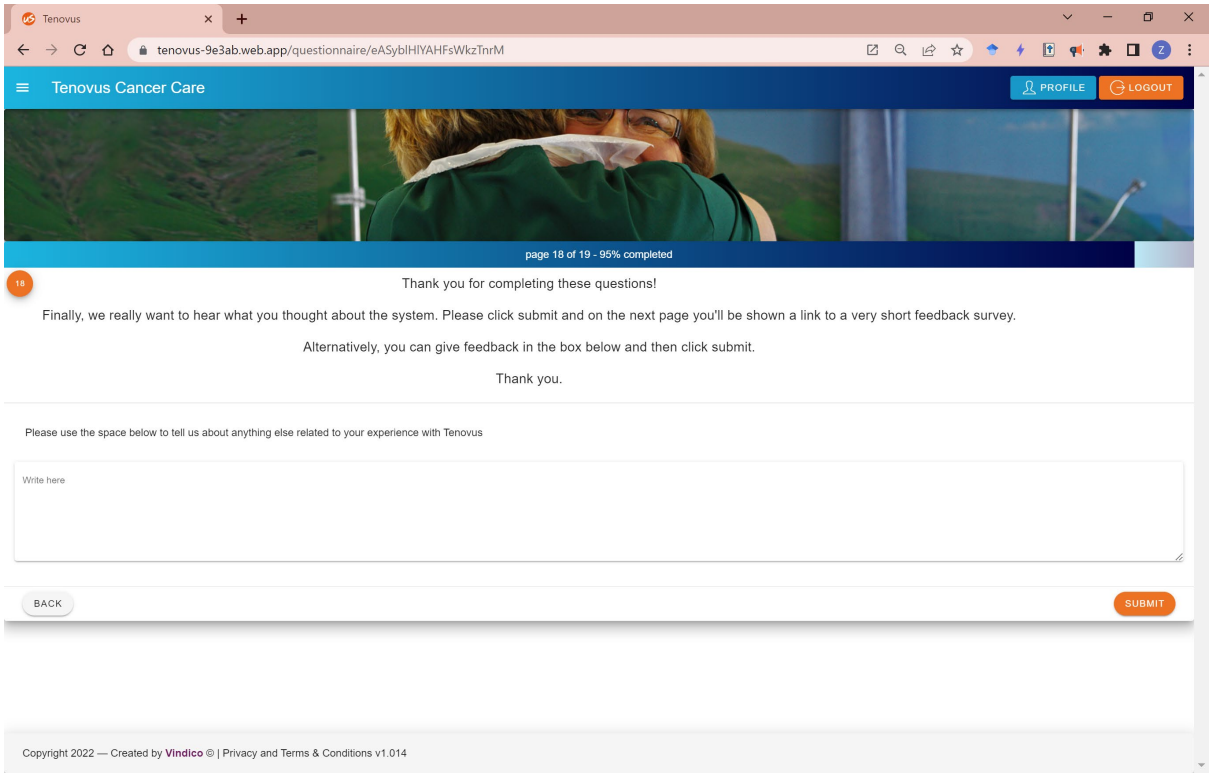
Item	Not at all/never 0	1	2	3	A great deal or all the time 4
Triggers					

The following situations make me think about the possibility of developing another cancer: 1. Television shows or newspaper articles about cancer, cancer or illness. 2. An appointment with my doctor or other health professional. 3. Medical examination (e.g. annual check-up, blood tests, X-rays) 4. Conversations about cancer or illness in general. 5. Seeing or hearing someone who's ill. 6. Going to a funeral or reading the obituary section of the paper. 7. When I feel less well physically or when I am sick. 8. Generally, I avoid situations or things that make me think about the possibility of developing another cancer					
Severity	Not at all/never 0	1	2	3	A great deal or all the time 4
9. I am worried or anxious about the possibility of developing another cancer. 10. I am afraid of developing another cancer. 11. I think it's normal to be anxious or worried about the possibility of developing another cancer 12. When I think about the possibility of developing another cancer, this triggers other unpleasant thoughts or images (such as death, suffering, the consequences for my family) 13. I believe that I am cured and the cancer will not come back 14. In your opinion, are you at risk of developing another cancer? 15. How often do you think about the possibility of developing another cancer? 16. How much time per day do you spend thinking about the					

possibility of developing another cancer? 17. How long have you been thinking about the possibility of developing another cancer?					
Psychological Distress	Not at all/never 0	1	2	3	A great deal or all the time 4
When I think about the possibility of developing another cancer, I feel: 18. Worry, fear or anxiety 19. Sadness, discouragement or disappointment 20. Frustration, anger or outrage 21. Helplessness or resignation					
Functioning impairments	Not at all/never 0	1	2	3	A great deal or all the time 4
My thoughts or fears about the possibility of developing another cancer disrupt: 22. My social or leisure activities (e.g. outings, sports, travel). 23. My work or everyday activities. 24. My relationship with my partner, my family or those close to me 25. My ability to make future plans or set life goals 26. My state of mind or my mood 27. My quality of life in general					
Insight	Not at all/never 0	1	2	3	A great deal or all the time 4
28. I feel that I worry excessively about the possibility of developing another cancer. 29. Other people think I worry excessively about the possibility of developing another cancer 30. I think I worry more about the possibility of developing another cancer, than other people diagnosed with cancer worry	4	3	2	1	0

about developing their cancer again					
Reassurance	Not at all/never 0	1	2	3	A great deal or all the time 4
When I think about the possibility of developing another cancer, I use the following strategies to reassure myself: 31. I call my doctor or another health professional 32. I go to the hospital or clinic for an examination 33. I examine myself for any signs of cancer					
Coping strategies	Not at all/never 0	1	2	3	A great deal or all the time 4
When I think about the possibility of developing another cancer, I use the following strategies to reassure myself: 34. I try to distract myself (e.g. do various activities, watch TV, read, work). 35. I try to get the idea out of my mind, to not think about it 36. I pray, meditate or do relaxation 37. I try to convince myself that everything will be fine or I think positively 38. I talk to someone about it 39. I try to find a solution 40. I try to replace this thought with a more pleasant one. 41. I tell myself “stop it”.					

Free text


Tenovus
tenovus-9e3ab.web.app/questionnaire/eASybIHlYAHFsWkzTnrM
Tenovus Cancer Care
PROFILE
LOGOUT
page 18 of 19 - 95% completed
18
Thank you for completing these questions!
Finally, we really want to hear what you thought about the system. Please click submit and on the next page you'll be shown a link to a very short feedback survey.
Alternatively, you can give feedback in the box below and then click submit.
Thank you.
Please use the space below to tell us about anything else related to your experience with Tenovus
Write here
BACK
SUBMIT
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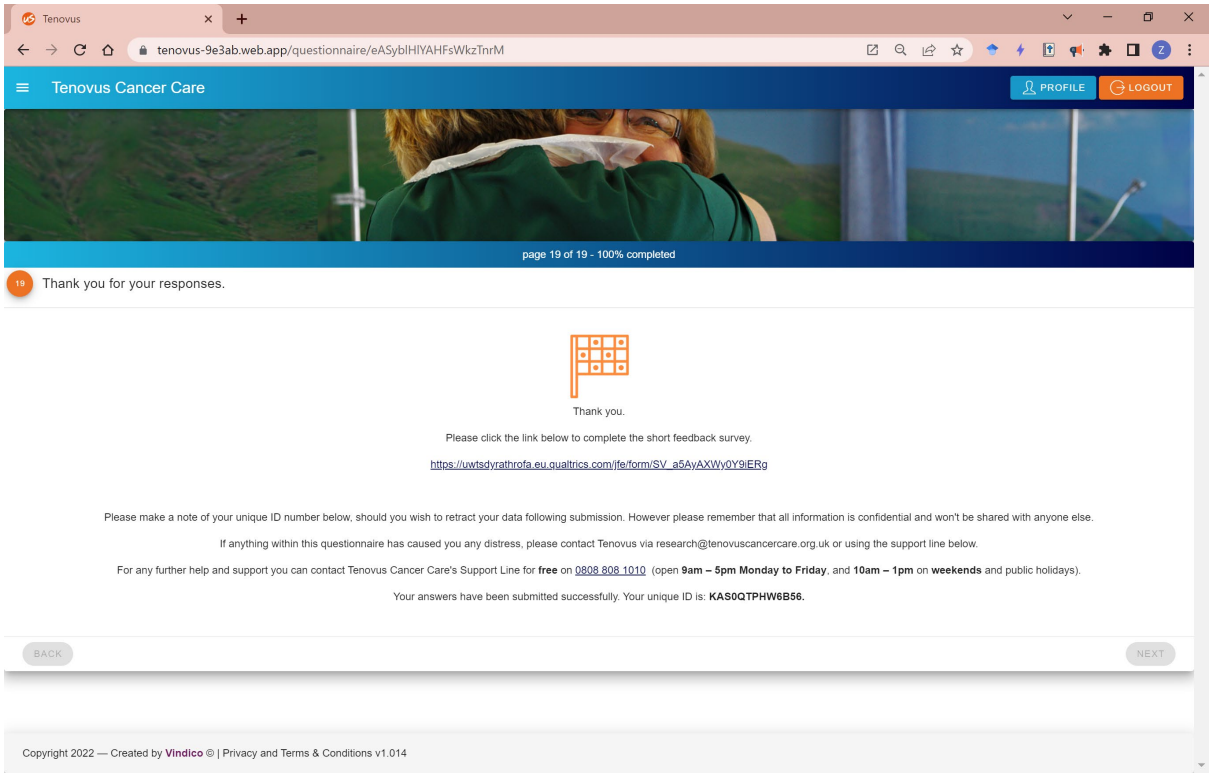
Debrief/Final Page



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