Facilitating practitioners to deliver self-management support to cancer survivors: development and co-design of a theory-based intervention informed by contexts and mechanisms

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Abstract

Background

Older cancer survivors have physical and psychosocial problems after completing cancer treatment which are not adequately addressed by secondary care teams. Enabling older cancer survivors to self-manage problems after cancer treatment is essential for optimising their health and wellbeing. This thesis aimed to design an intervention to facilitate primary care teams to provide self-management support to older cancer survivors.

Methods

Underpinned by scientific realism and behavioural science, this research involved three empirical studies: a cross-sectional study to estimate the prevalence of cancer treatment-related problems in older cancer survivors and overall care satisfaction, a realist review, and a co-design study to understand and address the barriers and enablers for facilitating primary care practitioners to provide self-management support.

Results

Half of older cancer survivors experienced physical and psychosocial problems after cancer treatment. Of these, 82% experienced physical, 69% psychological and 51% social problems. Perceived support from secondary care teams to manage physical, psychological and social problems was rated as adequate by 64%, 50% and 28%, respectively.

Key enablers for facilitating practitioners to provide self-management support were knowledge and communication skills to engage cancer survivors in discussions about self-management, practitioners feeling that their role and responsibilities included self-management support, the organisation prioritising self-management support, and health system configuration to integrate self-management support into routine care.

A structured pathway was co-designed to facilitate primary care teams to provide self-management support. This will involve using the knowledge and skills of existing team members to identify patients with unmet needs who may benefit from additional support, identifying local self-management resources and signposting patients to existing provision of information and care, and a mechanism for annual patient follow-up.

Conclusion

The intervention developed maximises the role of existing primary care teams and optimises current processes. The next step is to operationalise the intervention and evaluate efficacy at facilitating delivery of self-management support.

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Abbreviations

Abbreviation	Meaning
BCTs	Behaviour Change Techniques
CMOCs	Context-Mechanism-Outcome configurations
LWBC	Living With and Beyond Cancer
MRC	Medical Research Council
NCSI	National Cancer Survivorship Initiative
NHS	National Health Service
PT	Programme Theory
PTs	Programme Theories
TDF	Theoretical Domains Framework
TTAT	Theory and Techniques Tool
UK	United Kingdom
US	United States

Initials

DB Debi Bhattacharya

HW Hattie Whiteside

JT Jo Taylor

KK Kumud Kantilal

WH Wendy Hardeman

Publications, presentations and grants

Thesis related publication

Realist review protocol for understanding the real-world barriers and enablers to practitioners implementing self-management support to people living with and beyond cancer

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Thesis related conference abstract publication

A survey of the prevalence of long-term systemic anticancer treatment side effects and satisfaction with care in older people living with and beyond cancer

Kantilal, K., Small, M., Karapanagiotou, E., Hardeman, W., Bhattacharya, D., Nov 2019, In: Journal of Geriatric Oncology, Volume 10, Issue 6, S85

Thesis related oral presentations

- Centre for advancement in realist evaluation and synthesis (CARES) 2020 Training Conference: Using the Theoretical Domains Framework to build programme theory
- Norwich Cancer Research Network 2020 inaugural Conference: Designing services for older people with cancer
- British Oncology Pharmacy Association 2020 Conference: DiSCO – designing services for cancer in older people
- International Realist 2021 Conference: Incorporating the theoretical Domains Framework to build relaist programme theories for interventions to support self-management
- British Oncology Pharmacy Association 2021 Conference: Facilitating healthcare practitioners to deliver self-management support in adult cancer survivors: a realist review

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- Health Services Research & Pharmacy Practice 2020 Conference: The prevalence of cancer treatment side effects: a survey of older cancer survivors
- Applied Research Collaboration East of England 2020 Showcase: Understanding the barriers and enablers to practitioners implementing self-management support to cancer survivors: a realist review
- British Oncology Pharmacy Association 2021 Conference: Facilitating healthcare practitioners to deliver self-management support in adult cancer survivors: a realist review
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  Mislang, A. R., Soto-Perez-De-Celis, E., Russo, C., Colloca, G., Williams, G. R., O'Hanlon, S., Cooper, L., O'Donovan, A., Audisio, R. A., Cheung, K-L., Sarrió, R. G.,

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Chapter 1 Background

1.1 Trends in the number of people living with cancer

The number of people diagnosed with cancer globally will increase by around 50%, from 19 million in 2020 to over 28 million in 2040 [1]. Worldwide, the most commonly diagnosed cancer is breast cancer, followed by lung, colorectal and prostate cancers. Numerous factors have contributed to the global burden of cancer. These include a growing and ageing population and increase in risk factors such as smoking, obesity, physical inactivity and poor diet [1]. Early detection and treatment advancements have led to improving global cancer survival rates, for example, the 5-year survival rate for breast cancer is up to 90% and for colon cancer up to 70% in high income countries, such as, the United States (US), Canada and Australia [2]. However, there is huge global variation in cancer survival. This is mainly attributable to differences in access to diagnostic services and treatment, and poor investment in health resources by governments in low- and medium-income countries, such as India, Angola and Brazil [3]. The global cost of cancer care to 12.9 million people in 2009 was around US$286 billion [4]. In the US alone, the cost of cancer care was projected to rise by 23%, from over $124 billion in 2010, to over $157 billion by 2020 [5].

In the United Kingdom (UK), the number of people living with cancer will grow from just under 3 million in 2020 to over 5 million in 2040 [6]. People living with cancer will account for approximately 8% of the UK population across all ages, and 24% of people aged 65 years and over, in 2040 [6]. A large majority of people in the UK will live for five years or more after being diagnosed with cancer, which will increase from around 61% in 2009 to 68% in 2040. The National Health Service (NHS) in England spent approximately £6.7 billion on cancer care in 2012/13, £1.5 billion of which was on medication to treat cancer, such as chemotherapy [7]. The annual cost of cancer care in England was projected to grow by 9%, rising to £13 billion in 2020/21 [8].

Older people, ≥ 65 years of age, account for a large proportion of adults living with cancer in the UK. Compared to 2009, the proportion of older people living with cancer is projected to rise from 63% to 77% by 2040. The most commonly diagnosed cancers in older people are breast and prostate cancers [6]. Figure 1 shows the projected growth in the number of older people diagnosed with cancer in the UK, from 2009 to 2040. Older people are at increased risk of side effects from cancer treatment, which is partly due to having other long-term conditions alongside cancer and normal ageing processes [9-11].

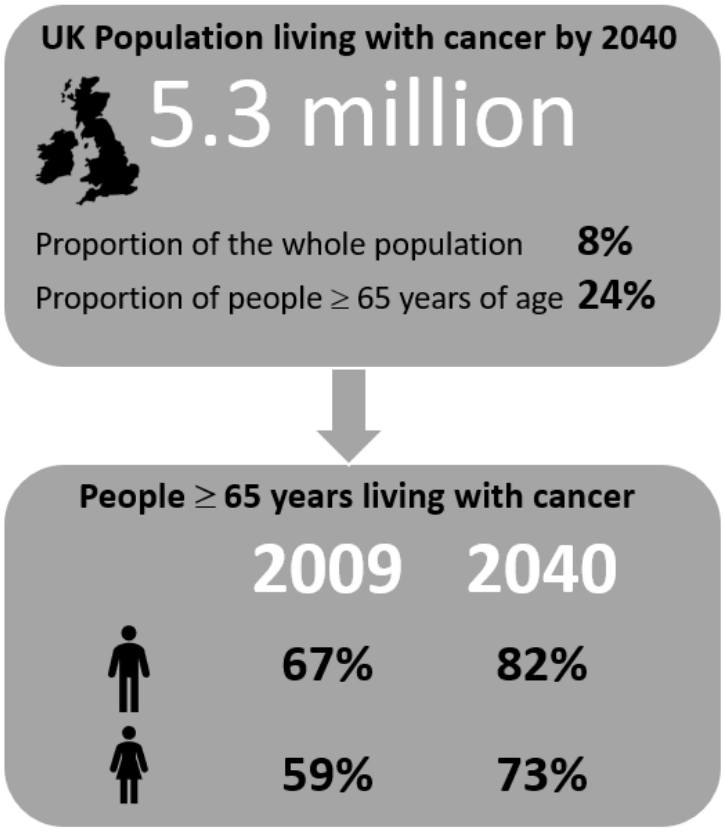

Figure 1: Percentage change in the number of older people living with cancer in the UK from 2009 to 2040 (Source: Maddams and colleagues 2012 [6])

1.2 Defining “cancer survivors” and “cancer survivorship”

1.2.1 Cancer survivor

The term “cancer survivor” was first described by a physician with cancer, Fitzhugh Mullen, in 1985 [12]. Believing that being cured/not cured did not capture the experiences of people

with cancer, he divided cancer into the three survival stages of acute, extended and permanent. Mullen referred to *acute survival* as the period after a cancer diagnosis and where people focused on treatment; *extended survival* was the period after completing treatment and where people focused on managing the physical and psychological consequences of treatment; and *permanent survival* was where cancer recurrence was unlikely and where people focused on dealing with the long-term effects of treatment. The US National Coalition of Cancer Survivorship, founded in 1986 by Mullen and others, defines a cancer survivor as someone from the time of a cancer diagnosis and for the rest of their life. This definition has been expanded to include family, friends and caregivers [13]. The US National Cancer Institute and American Cancer Society have adopted the definition used by the National Coalition of Cancer Survivorship to define a cancer survivor as a person with cancer from diagnosis to death [14]. However, others have used the end of active treatment as the point at which a person becomes a cancer survivor [15, 16]. For example, the European Organisation for Research and Treatment of Cancer Survivorship Task Force defines a cancer survivor as a person with cancer who has completed their primary treatment, but may be on on-going maintenance treatment [17]. In their Survivorship Care Compendium, the American Society of Clinical Oncology define a cancer survivor as an individual who has completed curative treatment or who is on maintenance or prophylactic treatment [18].

In England, the National Cancer Survivorship Initiative (NCSI) is a partnership between the Department of Health and the charity Macmillan Cancer Support. It was established in 2010, following the publication of the 2007 Cancer Reform strategy [19] to consider how survivorship care should be tailored to meet individuals' needs. The NCSI vision document broadly defined cancer survivors as "those who are undergoing primary treatment, those who are in remission following treatment, those who are cured and those with active or advanced disease" [20]. This definition is similar to the one adopted in the US and encompasses the experiences of a wide range of people diagnosed with cancer but

excludes those receiving end-of-life care. Criticism of the definition by the NCSI centres around it not being evidence-based and the lack of validation against the experiences of people living with cancer in the UK [15].

The UK NCSI acknowledged that not all people living with a diagnosis of cancer may identify with being a "survivor" [20]. Indeed, a qualitative interview study of the term "cancer survivor" in the UK, among 40 people at least 5 years after a diagnosis of breast, colorectal or prostate cancer, found that the term was not acceptable by the majority [21]. The NCSI introduced an alternative phrase, "living with and beyond cancer" (LWBC) [20, 22], which has been widely adopted in the UK by NHS England and the National Cancer Research Institute. NHS England's LWBC Clinical Advisory Group meet regularly to share good practice to improve the lives of people diagnosed with cancer [23]. Likewise, the National Cancer Research Institute partnered with the James Lind Alliance in 2018 to identify the top research priorities for LWBC. This resulted in establishing a LWBC Group to provide oversight on research related to LWBC [24].

1.2.2 Cancer survivorship

Similar to "cancer survivor", the related term "cancer survivorship" has numerous definitions, with no clear agreement among healthcare practitioners [25]. Further, cancer survivorship can be viewed from different perspectives, such as, (1) a timeframe, (2) treatment outcome, (3) stage/phase or (4) process [26]. Table 1 provides examples of the different approaches for defining survivorship and why it may not be applicable to all people due to the heterogenous nature of cancer and its treatment.

Table 1: Overview and critique of approaches used to define cancer survivorship

Approach to define survivorship	Examples	Critique to the approach
Timeframe	Time since diagnosis e.g., 2, 5, or 10 years	Survival rates vary between different types of cancers e.g., 98% of people diagnosed with testicular cancer will

		survive 10 years after a diagnosis, whereas, the 10-year survival rate for people with pancreatic cancer is 1% [27].
Treatment outcome	Presence or absence of cancer e.g., no evidence of cancer, complete remission, cure	May be misleading if patients continue to take long-term maintenance treatment to control the cancer or treatment-related side effects.
Stage or phase	Different phases/stages of treatment or progression of cancer e.g., after completion of primary active treatment, cancer recurrence	Some people may have a recurrence of the original cancer, whereas others may develop a second cancer. Cancer treatment could cause late-effects or increase the risk of developing other health conditions e.g., heart disease, diabetes, osteoporosis.
Process	Experience of living through different stages of cancer	While some people may recover from physical consequences, others may be faced with long-term emotional and social consequences of cancer and its treatment

The US Institute of Medicine defines survivorship as beginning at the point of completing primary (the first) cancer treatment and continuing until cancer recurrence, a second cancer or death [28]. The Institute of Medicine has identified the following components essential for optimising survivorship care [28]:

- Prevention of recurrent and new cancers and other late effects.
- Detection of recurrent and new cancers, and assessment of late effects of cancer and its treatment.
- Management of the long-term and late effects of cancer and its treatment.
- Co-ordination of care between providers across different settings to meet the health needs of survivors.

In England, survivorship is defined as the period after completing initial treatment, regardless of whether the person is free from cancer at that time [20]. The five shifts described by the NCSI in 2010 regarding the approach to survivorship care are shown in figure 2 [20].

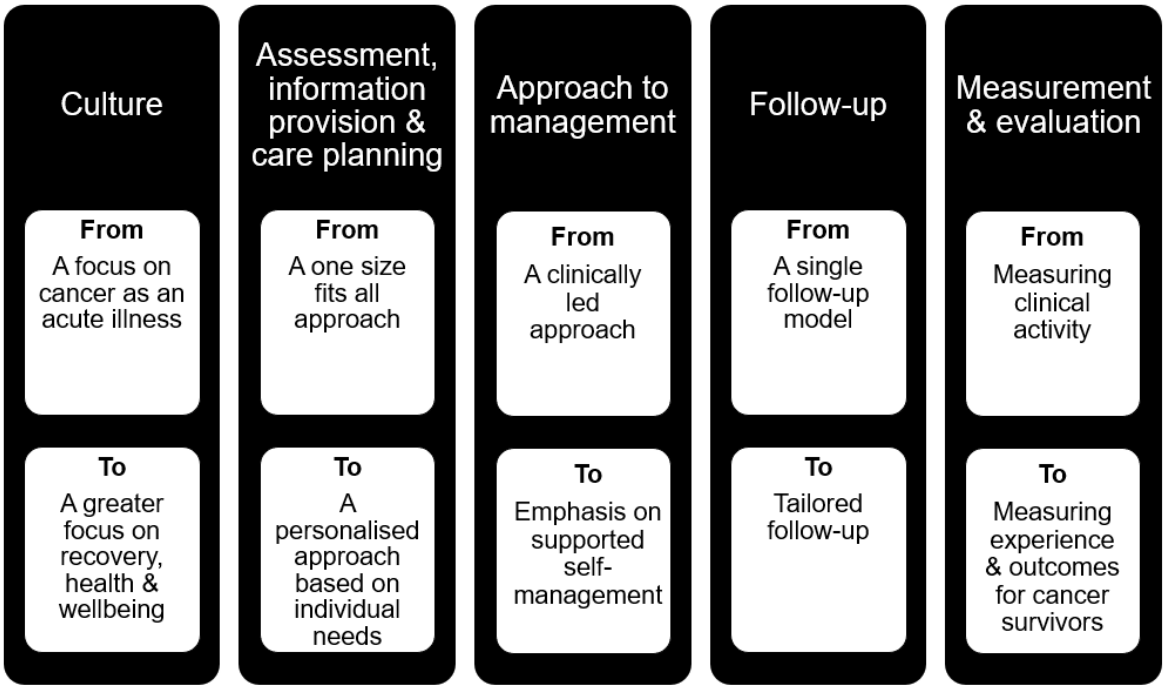

Figure 2: Five shifts in the approach to care and support of cancer survivors in the UK

1.2.3 Definitions of "cancer survivor" and "cancer survivorship" used in this thesis

In this thesis, the definition adopted for a "cancer survivor" is someone who has completed initial cancer treatment regardless of whether they are prescribed on-going maintenance treatment and not receiving end-of-life care.

The definition adopted for "cancer survivorship" in this thesis is the one generally used in the UK, which is the period after completing initial cancer treatment, regardless of whether cure has been achieved.

1.3 Consequences of cancer and its treatment

The main types of treatment for cancer are surgery, radiotherapy and drug therapy, referred to as systemic anticancer therapy. Systemic anticancer therapy includes cytotoxic chemotherapy, hormonal therapy, targeted therapy and immunotherapy. For simplicity, the following terms are used in this thesis:

- cancer treatment – to describe all types of treatment for cancer, which includes surgery, radiotherapy and drug therapy
- anticancer treatment – to describe systemic anticancer therapy, which is drug therapy only.

Cancer and its treatment can affect multiple aspects of a person's life [29-32]. Figure 3 provides the four domains of life affected with examples.

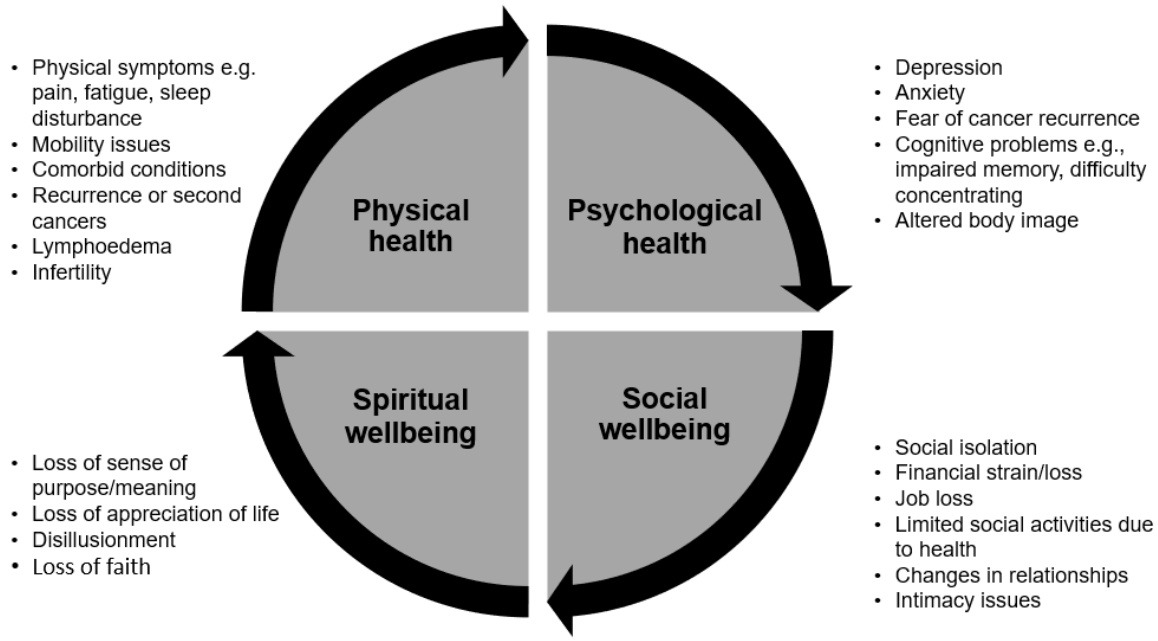

Figure 3: Common long-term and late effects of cancer and its treatment

Effects of cancer and its treatment vary depending on treatment-related factors, such as, type, dose, and duration of treatment, and patient-related factors, such as, age, genetics, organ function and co-existing conditions [33]. Some effects are acute and temporary, e.g., hair loss, nausea and vomiting related to anticancer treatment. Other effects can begin during treatment and last for months or years after completing treatment, termed long-term effects. Examples of long-term effects include fatigue, peripheral neuropathy, infertility and memory problems. Some long-term effects will resolve over time, while others may intensify or become permanent e.g., cognitive dysfunction and infertility, respectively. Long-term

effects of cancer treatment can be burdensome, with 27% of cancer survivors reporting three or more effects after completing treatment [34]. Poor management of long-term effects can lead to reduced quality of life, nonadherence to follow-up care and impaired ability to work [35]. However, being diagnosed with cancer can also result in positive changes in some people, e.g., enhanced self-esteem, increased appreciation for life, increased spirituality and improved relationships with relatives [36].

Some effects occur months to years after completing treatment, termed late effects, and include second cancers, heart disease, lung disease, and osteoporosis. Having a cancer diagnosis increases the likelihood of developing a second or subsequent cancer in about 20% of cancer survivors [37]. Late effects can affect all aspects of a cancer survivor's life, including mental and physical health, ability to work, personal relationships, self-esteem and body image and lead to increased use of health and social care services [38].

The period after completing cancer treatment can be challenging for many and has been associated with cancer survivors feeling abandoned, vulnerable and 'lost' [28, 39]. Cancer survivors and their families struggle with adjusting to usual routines, such as work and family life due to fears of dying and uncertainty of treatment outcomes and the future [40]. Supportive care services are often spread across multiple settings and delivered by multiple providers, which could make it challenging for survivors to access the right services for their unique informational, medical, emotional, spiritual, social and practical needs [41].

Described below are the common long-term and late effects of cancer and its treatment. They are presented as those common among all adult cancer survivors and then looks specifically at the problems faced by older adults, who account for a large proportion of cancer survivors.

1.3.1 All adults

Long-term effects – starting during and lasting month/years after treatment completion

Four common long-term effects experienced by cancer survivors after completing cancer treatment regardless of cancer type are fatigue, depression, memory problems and sexual dysfunction [30].

It is estimated that about a third of cancer survivors experience fatigue post treatment [42]. Up to 20% of breast cancer survivors may have fatigue for as long as 10 years after cancer treatment [43]. Fatigue is associated with pain, sleep disturbance, anxiety and depression and, if persistent, can impact quality of life, physical functioning and symptom management [42]. Interventions that can help with fatigue management include medication, such as antidepressants and anxiolytics, and non-drug interventions, such as, physical activity, yoga and mindfulness practice [33].

The prevalence of depression in cancer survivors is estimated at about 20-30% [36]. The risk factors for depression among cancer survivors include younger age, female sex, having other health conditions and prior history of depression [30]. Left untreated, depression can result in lack of engagement with survivorship care, poor quality of life and disrupt return to usual activities, such as work [44]. Both drug and non-drug interventions have proven beneficial in treating depression, such as, antidepressants and cognitive behaviour therapy, respectively [33].

Neurocognitive problems which relate to problems with memory, thinking clearly and focusing attention may affect about 14% of cancer survivors, and is commonly referred to ‘chemo brain’ or ‘chemo fog’ [30]. The risk factors for neurocognitive problems include older age, changes in brain chemistry and structure and prolonged intensive anticancer treatment [30, 33, 45]. Neurocognitive impairment can impact cancer survivors’ quality of life, ability to

perform daily activities, ability to adhere to treatment and is associated with negative emotional states, such as anxiety and depression [46]. Non-drug interventions, such as cognitive behavioural therapy, Tai Chi, and memory training strategies have helped in the management of neurocognitive problems [30, 45].

Despite sexual dysfunction being estimated to occur in 40-100% of cancer survivors, healthcare practitioners often fail to raise and address issues related to sexual concerns [30, 47]. Sexual problems commonly reported include decreased desire, arousal disorders, pain mainly in women and erectile dysfunction in men. Risk factors for developing sexual problems include older age, negative body image, fatigue, stress, medications and hormonal changes [33, 47]. Both drugs, such as, hormonal therapy and antidepressants, and non-drug interventions, such as counselling, are recommended to support cancer survivors experiencing sexual problems [33, 47].

So far, the common long-term side effects are described which occur during treatment and could last months to years after completing treatment. Other effects, can occur months to years after completing cancer treatment, termed late effects. Examples of late effects are provided below.

Late-effects – occurring months/years after completing treatment

Late effects, reported in about 40% of cancer survivors, are commonly associated with radiotherapy and anticancer treatment and include second cancers, osteoporosis and organ dysfunction, with examples provided in table 2 [33, 45, 48]. Late effects can also occur as a result of patient-related factors, such as, age, genetic factors, other health conditions and health behaviours, such as, smoking, alcohol, obesity and physical inactivity. Health promotion and prevention is therefore essential to reduce risks of late effects in cancer survivors [35]. Cancer survivors are often not provided with information about potential late effects of cancer treatment and therefore feel ill prepared to manage them [38].

Table 2: Examples of late effects of cancer treatment

Potential late effects	Cancer treatment	Examples
Cardiac dysfunction	Radiotherapy Anticancer treatment	Myocardial infarction Congestive heart failure
Pulmonary dysfunction	Radiotherapy Anticancer treatment	Restrictive lung disease Exercise intolerance
Osteoporosis	Anticancer treatment	Fractures
Second cancers	Radiotherapy Anticancer treatment	Leukaemia, solid cancers Myelodysplastic syndromes,

Financial burden among cancer survivors

Cancer survivors not only experience physical and psychosocial effects of cancer and its treatment but may also face financial hardship. The term 'financial toxicity' has been used to describe the financial burden experienced [49], which can significantly impact cancer survivors' quality of life and psychological wellbeing [50]. Financial toxicity has been self-reported by 16 to 73% of cancer survivors [51] with variations depending on country and health system. As expected, increased financial hardship of cancer survivors have been reported in countries where healthcare is provided through a combination of private health insurance and public health systems, such as, the US and some European countries. However, financial expenses have also been incurred by cancer survivors in the UK NHS, despite healthcare being mostly free [52, 53].

1.3.2 Older adults

Older cancer survivors have poorer health, quality of life and functional status and more comorbidities (more than one illness at the same time), disability, frailty and geriatric syndromes (e.g., dementia, falls, incontinence, failure to thrive) compared to older adults without cancer [54]. The physical decline associated with ageing, such as, decreased kidney function, decreased bone and muscle mass, and impaired glucose tolerance can affect efficacy and tolerability of anticancer treatment. The psychosocial risks associated with ageing, such as, depression, anxiety and inadequate social support, can increase older adults' vulnerability to long-term and late effects of anticancer treatment [54]. The long-term

effects experienced by older cancer survivors may also be compounded by the normal changes associated with ageing. For example, common cancer treatment-related long-term effects, such as fatigue, decrease in cognitive function, peripheral neuropathy and bone-health issues, e.g., osteoporosis, could easily be dismissed as symptoms associated with ageing [54, 55]. Older cancer survivors may have different goals compared to younger adults, for example, younger adults may focus on prolonged survival whereas, for older survivors independent functioning may be a priority [33].

Older adults with cancer have a higher prevalence of comorbid conditions compared to those without cancer [56]. In the UK, it is estimated that 70% of adults over the age of 65 years with a cancer diagnosis have at least one other health condition that may increase the risk of anticancer treatment-related toxicity [8, 9]. Having cancer and other comorbid conditions are associated with increased risk of anticancer treatment-related toxicity and hospitalisation, decreased physical functioning and poorer quality of life in older cancer survivors [9, 10]. Furthermore, anticancer treatment can result in new comorbidities, such as heart problems, neuropathy and kidney problems [9].

Despite older adults making up the majority of cancer survivors, information regarding their supportive care needs after completing anticancer treatment is limited [57-59]. Systematic reviews of the unmet needs of older adults are scarce and have focused on the times during or just before starting anticancer treatment. Reviews have excluded older adults who have completed anticancer treatment despite consequences potentially extending long after anticancer treatment is completed [60, 61]. The needs of older adults during anticancer treatment will likely differ from those who have completed anticancer treatment. Growing research and advocacy work shows that effective strategies need to be developed to help older cancer survivors manage their own health after anticancer treatment [39]. Understanding the size of the unmet needs of older adults who have completed anticancer treatment is vital before any supportive care strategies can be developed.

1.4 Follow-up care of cancer survivors

Many countries are reconfiguring their health systems and introducing various models to support implementing high quality follow-up care to cancer survivors after they complete cancer treatment. Models of care have been mainly influenced by the design of healthcare delivery systems and healthcare payment structures [62]. Survivorship care models have evolved from a focus on detection of recurrent or new cancers to a more holistic approach with an emphasis on managing long-term effects of cancer and its treatment, preventing or mitigating late effects of treatment, encouraging healthy lifestyle behaviours and supporting self-management [63]. With increasing numbers of older adults living with cancer alongside other health conditions, there is growing recognition that survivorship care will need to include comorbidity management and be delivered by multidisciplinary teams [64]. However, the optimal model for the care of older cancer survivors has not been described [55].

In England, follow-up care of adult cancer survivors usually involves 3 to 5 years of surveillance under the care of the hospital cancer care team. Cancer survivors are then discharged from hospital follow-up to primary care where they are managed by the general practice team [65]. The current approach to hospital- and primary care-based follow-up care in England are provided below, including proposals for future follow-up care.

1.4.1 Hospital-based follow-up in England

A stratified follow-up pathway was first proposed in 2010 by the NCSI, for cancer survivors who had completed cancer treatment, based on risk of cancer recurrence, the likelihood and severity of cancer treatment-related consequences and their holistic needs [20]. The approach aimed to identify cancer survivors that needed regular hospital visits to monitor and manage the consequences of cancer treatment from those that could self-manage with limited follow-up visits. This approach would ensure appropriate use of NHS resources,

whilst adequately meeting cancer survivors' needs. The pilot testing of stratified pathways across 14 sites in England, found that self-management could meet the needs of about half of the patients. Fewer hospital-based appointments were needed for those on the self-management pathway, increasing healthcare productivity with a projected saving for the NHS in England of about £90 million over 5 years [64].

In 2015, the Independent Cancer Taskforce proposed roll-out of stratified pathways in its report 'Achieving world-class cancer outcomes: a strategy for England' [8]. One of the six proposed priorities related to cancer survivors having access to one of two stratified follow-up pathways: professional-led or patient initiated. The stratified follow-up pathways, illustrated in figure 4, are currently being implemented across England for people with breast, colorectal and prostate cancers. Stratified follow-up is facilitated by the following interventions: personalised care and support plan based on a Holistic Needs Assessment, End of Treatment Summary, Health and Wellbeing information and support, and a Cancer Care Review. Most personalised stratified pathways are delivered in the hospital setting and are in line with the ambitions of the NHS Long Term Plan to empower people to manage their cancer and its impact on their daily lives [66].

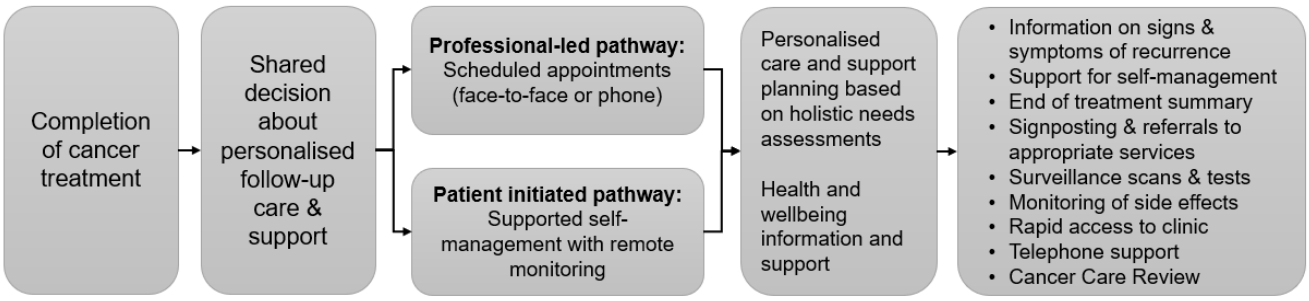

Figure 4: Overview of the personalised stratified follow-up pathway for adult cancer survivors in England

1.4.2 The role of primary care in the follow-up of cancer survivors in England

Cancer survivors have indicated that primary care teams play a key role in managing cancer treatment-related consequences, comorbidities and offering personalised holistic support

[67]. The other benefits of primary care are convenience, familiarity and knowledge of the survivors' family situation [68]. General practitioners also consider themselves well-placed and willing to play a role in follow-up care of cancer survivors [69]. However, the recognised barriers to involving primary care in cancer survivorship include cost of care provision, time limitations, limited expertise and confidence and inadequate communication between primary and secondary care [69, 70].

The role of primary care in following-up cancer survivors can be viewed from two points in time: (1) when the cancer survivor completes cancer treatment and is still under the care of the secondary care team, usually for 3 to 5 years, and (2) when the cancer survivor is discharged from secondary care to the primary care team. During the first 3 to 5 year follow-up period, the role of the primary care team is limited to receipt of End of Treatment Summaries and conducting Cancer Care reviews, which are described in table 3. The role of the primary care team in supporting cancer survivors once discharged from secondary care has not yet been clearly defined [68].

Table 3: Characteristics of interventions used in personalised stratified follow-up care of cancer survivors in England

Intervention	Intervention description	Delivery		Target audience and purpose
		By	When	
End of Treatment Summary	Individualised, written summary of the diagnosis, treatment and follow-up plan.	Secondary care cancer care team e.g., oncologist, clinical nurse specialist	At the end of each treatment phase.	Cancer survivor: A record of treatment and intended follow-up plan. Survivor's general practitioner: Improve communication between secondary and primary care teams. Raise awareness of treatment received and information about potential long-term consequences of treatment to facilitate tailored support from primary care.
Cancer Care Review	Discussion between survivor and their primary care team about treatment,	Primary care team, e.g., general practitioner or practice nurse	Before April 2021: Within 6 months of a cancer diagnosis. From April	Cancer Survivor: Opportunity to discuss ongoing needs and understand what support is available in their community to support self-management. Primary care team: Offer

	needs, recurrence, consequences of treatment and actions to mitigate them. The discussion is usually informed by the contents of the End of Treatment Summary.	2021: Within 3 months of a cancer diagnosis and within 12 months of receiving treatment.	personalised support to cancer survivors and signpost to relevant local services, if needed.

The strengths of primary care are care continuity, care coordination and comprehensive coverage. Primary care teams are thus well positioned to optimising ongoing cancer survivorship care to people discharged from secondary care [68]. Primary care teams can play a vital role in supporting cancer survivors to identify and manage the long-term and late effects of cancer treatment, providing or facilitating psychosocial support, detecting cancer recurrence and offering general health and wellbeing support for improving overall quality of life of cancer survivors [68]. This is especially important for older cancer survivors living with complex multiple health conditions.

Various strategies have been proposed to support integration of survivorship care into primary care. These include availability of guidelines, education, effective communication between primary and secondary care teams, prompt access to secondary care, robust monitoring systems and adequate resources [68]. Multiple models for delivery of survivorship care in primary care have been proposed and include primary care-led follow up, a shared care approach between primary and secondary care and nurse-led clinics using remote follow-up or outreach clinics based in the community, which will need testing [68, 71].

1.5 Influences on unmet needs of cancer survivors

This section summarises the current understanding of experiences of cancer survivors and the state of cancer survivorship care in the UK. The number of cancer survivors is growing,

due to treatment advances and the ageing population. A large proportion of survivors are aged 65 years or more and living with cancer alongside other chronic conditions, such as diabetes, arthritis and heart disease. Despite a commitment by the NHS to improve the lives of people living with and beyond cancer, many still face multiple unmet physical, psychosocial and practical needs. To meet cancer survivor needs and to ensure that NHS resources are used effectively, much effort is underway to re-design cancer services. The current emphasis is on transforming secondary care-led follow-up of cancer survivors, with some integration of primary care. Key initiatives include providing tailored support by multidisciplinary teams that meet the holistic needs of survivors, with an emphasis on empowering people to play an active role in their own health and wellbeing, if possible.

This understanding is represented by a framework, which is shown in figure 5, to highlight the key unmet needs of people post cancer treatment: managing the psychosocial consequences of cancer, dealing with the physical consequences of cancer treatment and negotiating the multiple services on offer within the NHS. The framework shows the influences on the unmet needs of cancer survivors at a policy-level. The framework reflects national policy that sets out changes needed in cancer services and the healthcare workforce to facilitate a shift from a medical-led approach to self-management by cancer survivors, with support from healthcare practitioners.

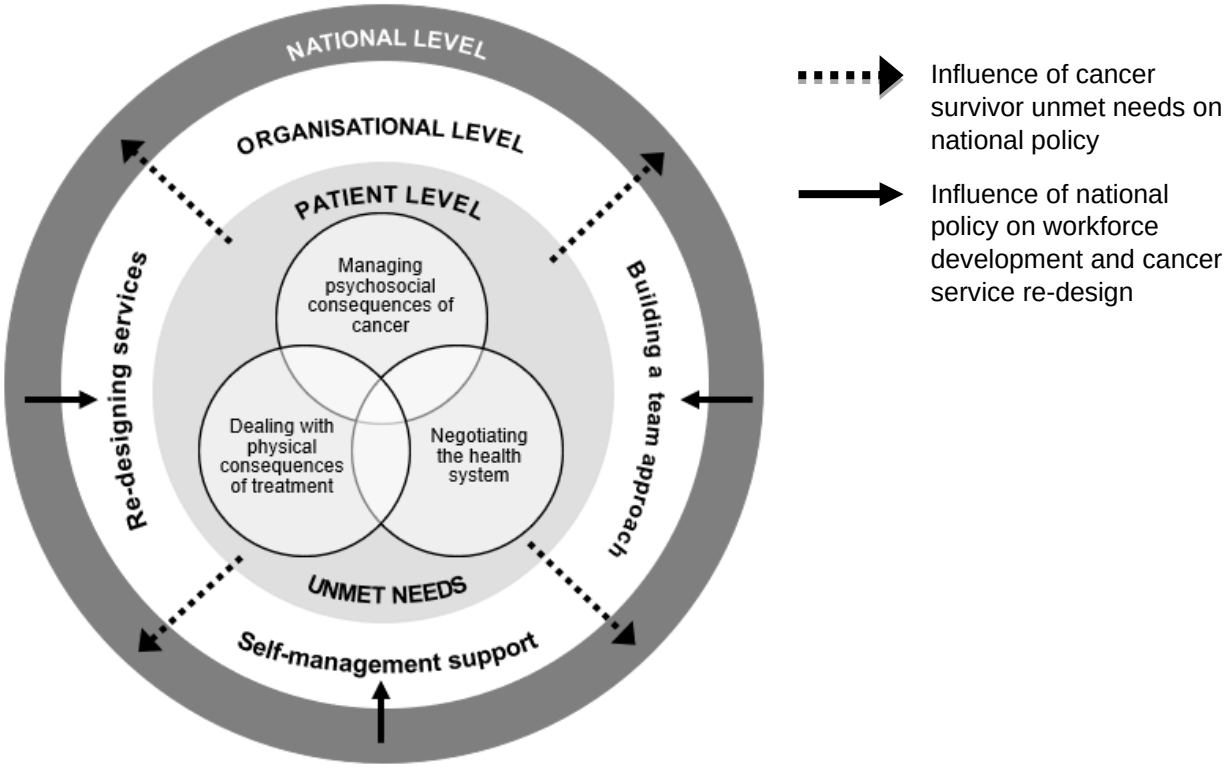

Figure 5: Framework of the influences on unmet needs of cancer survivors

1.6 Supporting self-management in cancer survivors

1.6.1 Self-management by cancer survivors

Given the huge emphasis on self-management in current NHS policy [8, 66], it is important to understand what self-management means in the context of cancer survivorship care. Figure 6 provides examples of key tasks in cancer self-management, which includes the patient actively managing and monitoring cancer treatment-related side effects, managing emotional aspects, adjusting to everyday life following treatment and navigating the healthcare system [72].

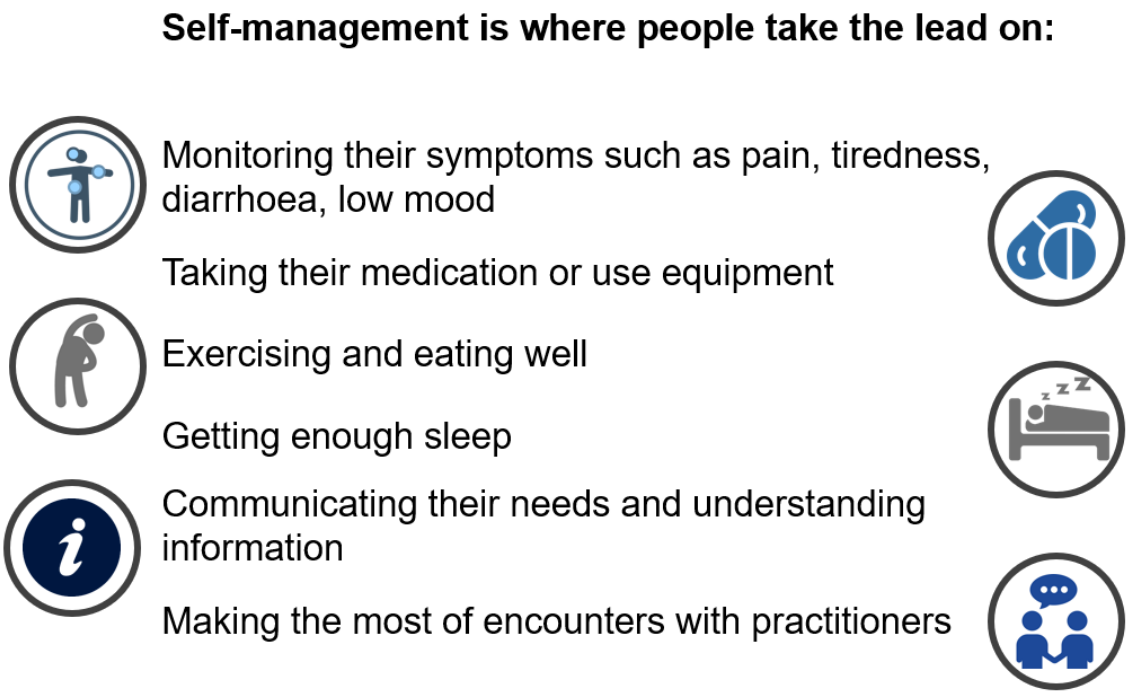

Figure 6: Examples of self-management activities by cancer survivors

1.6.2 Self-management support in cancer survivorship care

Strategies used by healthcare practitioners to increase patient knowledge, skills and confidence to self-manage is termed self-management support [39]. Self-management support interventions may directly target patients to support them to self-manage, by providing information and practical support for everyday activities. An alternative strategy is interventions targeting healthcare teams to provide self-management support to patients. These have included provision of training, feedback and financial incentives [73, 74]. Multiple healthcare practitioners may be involved in self-management support, which could be delivered across different healthcare settings and voluntary organisations. Moreover, these interventions could be provided through one-to-one or group interactions, with or without the use of digital technology and produce outcomes at patient-, practitioner- or service-levels.

The aims of self-management support in cancer survivorship care are to optimise health outcomes, accelerate recovery after cancer treatment and minimise any potential long-term consequences of cancer and its treatment [75]. Emerging evidence suggests that self-

management support can benefit cancer survivors by reducing physical and psychological consequences of cancer and its treatment and improving quality of life [76].

Despite being emphasised in policy agendas, self-management support has failed to become routine practice in cancer care [75, 77, 78]. Systematic reviews have focused on self-management support interventions targeting cancer survivors [77, 79-82]. These interventions tend to attract cancer survivors who are more affluent, educated and already self-managing well [83]. Interventions aimed at enhancing practitioner capability, opportunity and motivation for delivering self-management support are arguably more likely to ensure equity of care and be sustainable [84, 85], yet the evidence for such interventions is sparse [76]. A mixed-method study recently conducted in three Canadian cancer centres identified components needed for self-management support interventions targeting practitioners [86]. The three intervention components identified were that a cultural shift was needed to allow healthcare practitioners to engage patients as partners in self-management discussions, healthcare practitioners needed to understand what self-management support meant and what it involved and that healthcare practitioners needed appropriate support, tools and skills to deliver self-management support services. This mixed-method study described very broad components with a mixture of different types of interventions at individual practitioner, practitioner teams and organisational levels. A systematic theory-based approach is needed to characterise these interventions and their components [87].

1.7 Thesis plan

1.7.1 Summary of the research gaps

Based on the available evidence, three research gaps were identified:

1. There is a lack of understanding of the size and impact of anticancer treatment-related problems in older adults, despite them making up the majority of cancer survivors. Understanding the extent of unmet needs among older adults who have

completed anticancer treatment is vital before any supportive care interventions can be developed.

2. There is clear emphasis on empowering cancer survivors to manage their health and wellbeing after completing cancer treatment, with support from healthcare practitioners. However, interventions aimed at enhancing healthcare practitioner capacity to support cancer survivors to self-manage are limited. Understanding of the barriers to and enablers for facilitating practitioners to provide self-management support to cancer survivors is a key step to inform the development of a supportive care intervention.
3. The needs of cancer survivors extend far beyond completion of treatment. Although systematic approaches exist for secondary care-led follow-up for the first few years after treatment completion, structured self-management support from primary care beyond this period is lacking. The role that primary care could play in supporting cancer survivors to self-manage after they are discharged from secondary care is unclear. Views of primary care practitioners are crucial to inform the design of an intervention based on an understanding of their role in supporting self-management.

1.7.2 Overall research aim and objectives

This thesis aimed to design an intervention, targeted at primary care practitioners, to deliver self-management support to older cancer survivors living with long-term consequences of anticancer treatment.

This aim was achieved through the objectives listed below:

1. Estimation of the prevalence of anticancer treatment-related side effects in older cancer survivors (*Chapter 3).*
2. Understanding of the barriers and enablers for facilitating healthcare practitioners to provide self-management support to cancer survivors (*Chapter 4).*

3. Designing an intervention with patients and healthcare practitioners in primary care to address the barriers to the delivery of self-management support to older cancer survivors in the community (C*hapter 5).*

Each objective is linked to the three studies conducted for this PhD, which are described in Chapters 3-5.

1.7.3 Thesis structure

This thesis comprises six chapters, outlined below:

Chapter 1: Background explored the current evidence related to the prevalence, experiences and follow-up care of cancer survivors after completing cancer treatment. Definitions for 'cancer survivor' and 'cancer survivorship' were provided, including the definitions used throughout this thesis. The key follow-up strategies for survivorship care in the NHS in England were summarised. A framework was introduced illustrating the influences on unmet needs of cancer survivors and the emphasis on self-management support as a key strategy to meet the needs of cancer survivors. The chapter ends with identified gaps in the evidence that informed the three studies in this thesis.

Chapter 2: Methodological approach and underpinning theory presents the methodological approach, behavioural frameworks and theories that have been applied in the studies in this thesis, including their justification, to inform the development of an intervention. The key steps of the Medical Research Council guidance to guide the intervention development are described. Realist approaches are introduced. How the Theoretical Domains Framework was applied to the realist review and intervention development is described. Finally, the importance of stakeholders in the co-design of interventions is outlined. A logic model is introduced as a visual representation of how the intervention was developed to address barriers to delivery of self-management support in primary care.

Chapter 3: Study 1 describes the **cross-sectional study** to estimate the prevalence of side effects in older adults after completing anticancer treatment, the extent to which the NHS in England are supporting them and their overall satisfaction with follow-up care. Perceived service gaps are identified and key domains to target during the intervention design are highlighted. The contribution of the study to the logic model is presented.

Chapter 4: Study 2 describes the **realist review** to improve understanding of the barriers and enablers involved in facilitating healthcare practitioners to deliver self-management support to cancer survivors. Five enablers to inform the intervention design are identified, expressed as statements called realist programme theories. The contribution of the study to the evidence and evolving logic model are presented.

Chapter 5: Study 3 explores the **experiences** of primary care and community pharmacy teams with respect to the barriers and enablers for providing self-management support to older cancer survivors. The chapter describes the development **and co-design** of an intervention to facilitate practitioners in primary care to support older cancer survivors to self-manage long-term consequences of cancer treatment. The practitioner behaviour and intervention techniques identified in the study are added to the logic model.

Chapter 6: Discussion summarises the research and findings of the studies to address the research aim and objectives. Strengths and limitations are presented. Personal reflections of doing the PhD are presented. Finally, implications for clinical practice, research and policy are considered.

Chapter 2 Methodological approach and underpinning theory

2.1 Introduction

Chapter 1 described the proportion of adult cancer survivors and characterised the nature and size of their unmet needs after completing cancer treatment. The role played by healthcare practitioners to support cancer survivors to self-manage long-term consequences of cancer and its treatment was introduced. An argument was presented for the potential role of primary care to support cancer survivors with self-management because of its accessibility and existing pathways and processes for supporting self-management in people living with other long-term conditions, such as diabetes or asthma. This will be achieved through developing a self-management support intervention targeted at healthcare practitioners.

Chapter 1 introduced the six chapters in this thesis. An initial logic model was generated to graphically represent how the key findings of each chapter contribute to the development of the intervention and is shown in figure 7. The purpose of the initial logic model will be to:

- Summarise the context in terms of current understanding of experiences of cancer survivors, and consequences of cancer and its treatment after completing treatment. Figure 7 shows the contribution of Chapter 1 in understanding the context to inform the intervention development.
- Identify the problem related to the supportive care of older cancer survivors. This will be populated from the findings in Chapter 3 (survey).
- Identify the determinants, i.e., barriers and enablers, for facilitating practitioners to deliver self-management support to cancer survivors, which will be derived from Chapter 4 (realist review).
- Identify the practitioner behaviours and associated strategies to address the barriers to supporting self-management in older cancer survivors and intervention development, which will be reported in Chapter 5 (co-design study).

- Consider potential outcomes of the proposed intervention. This is included for completion of the logic model but is outside the scope of this PhD.

Chapter summaries for chapters 3-5 will include the tentative logic model and show the contribution of that chapter to populating the different aspects of the logic model. The final logic model will be presented in Chapter 6, showing contributions from all chapters. It could be used to support refinement of the intervention and identify potential outcomes to guide future research in self-management support interventions targeted at healthcare practitioners in the cancer survivorship setting.

This chapter summarises why self-management support interventions are complex (section 2.2). It then provides a brief overview of the four phases involved in complex intervention development and evaluation, i.e., development, feasibility/piloting, evaluation and implementation, based on guidance published by the UK Medical Research Council (MRC) in 2008 (section 2.3) [88]. The MRC produced new draft guidance in 2018 which includes actions to take during complex intervention development. These ten actions of healthcare intervention development are presented. Using recent guidance on how to develop complex healthcare interventions [89], the actions used for developing the intervention in this thesis are highlighted, with emphasis on three key actions: articulating programme theory, understanding context and involving stakeholders (section 2.4). Finally, the two approaches used to articulate programme theory, understand context and involve stakeholders during intervention development are presented. These two approaches are scientific realism (section 2.5) and co-design (section 2.7). In addition, the underpinning theoretical framework for developing the intervention, the Theoretical Domains Framework (TDF), reported in this thesis is introduced (section 2.6). An overview of each approach and the TDF is presented, together with how they will be used and the rationale for their selection will be given.

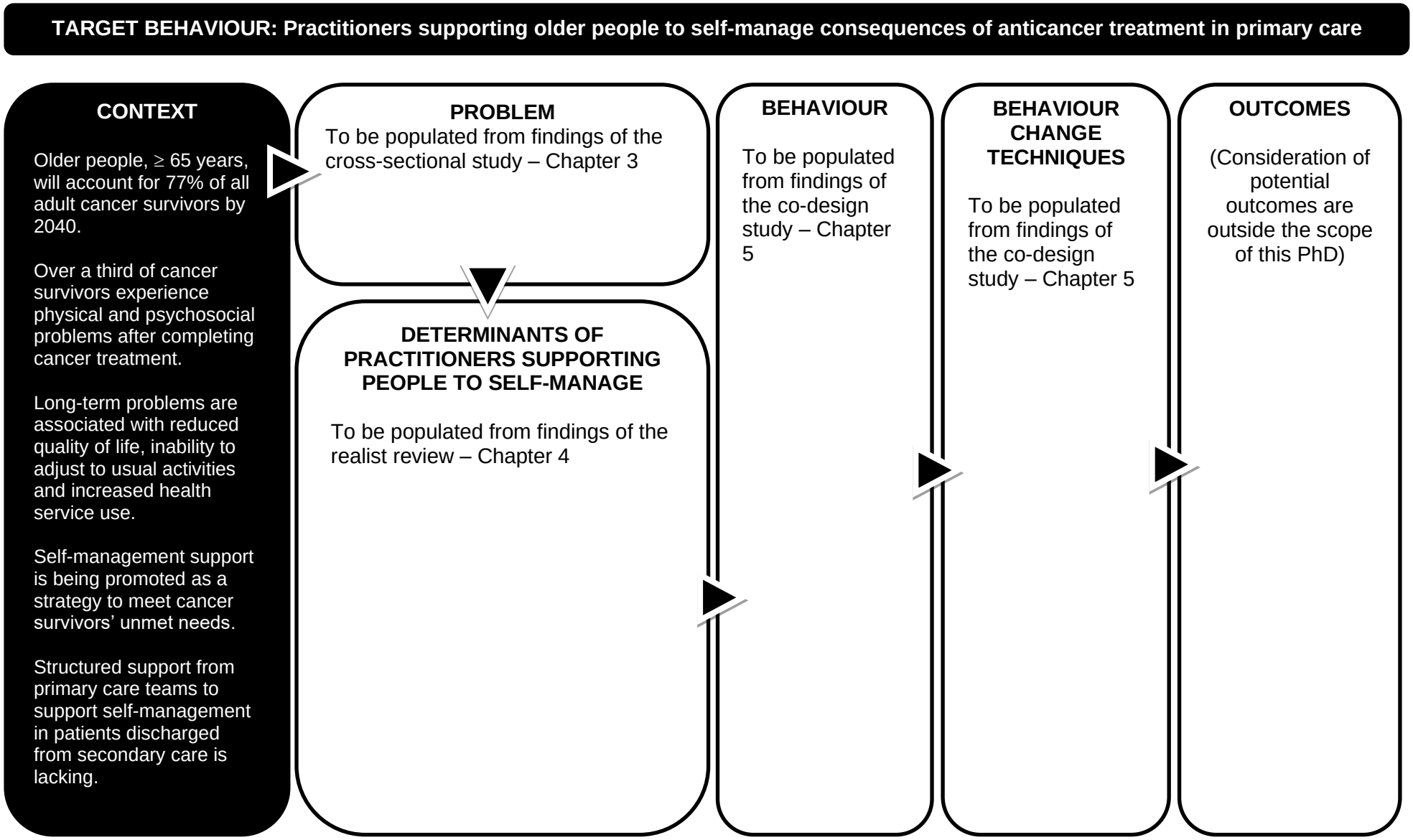

Figure 7: Tentative logic model: Facilitating primary care healthcare practitioners to provide self-management support to older cancer survivors

2.2 Self-management support is a complex intervention

Complex interventions have been defined as having a number of interacting components [88]. These include new behaviours by those delivering the intervention, e.g., practitioners providing tailored support and information to patients, and by those receiving the intervention, e.g., patients increasing their physical activity. Complex interventions may target numerous groups or organisations across various settings, e.g., primary, secondary or community care settings, and can have various outcomes, at patient, practitioner or health system levels. Complex interventions need to be developed in a way that produces an effective intervention that can be widely adopted across different contexts and settings [89].

The facilitation of self-management support is regarded as a complex intervention [90] for several reasons. Firstly, self-management support is dependent on the skills of the practitioner delivering the intervention and the engagement of those receiving the intervention. Secondly, self-management support can have a range of outcomes that are patient-focused, e.g., confidence in managing consequences of treatment, practitioner-focused, e.g., improved patient quality of life, or service-related, e.g., reduction in clinic appointments. Finally, self-management support needs to be tailored to the setting the intervention is being delivered from and to the needs of the patient.

2.3 The Medical Research Council guidance for intervention development and evaluation

The UK MRC published guidance for developing and evaluating complex interventions in 2000 [91], which were later updated in 2008 [88]. The 2008 guidance describes the four phases involved in intervention development and evaluation, which are intervention development, feasibility/piloting, evaluation and implementation. The MRC guidance lists several key steps for each phase, which are illustrated in figure 8.

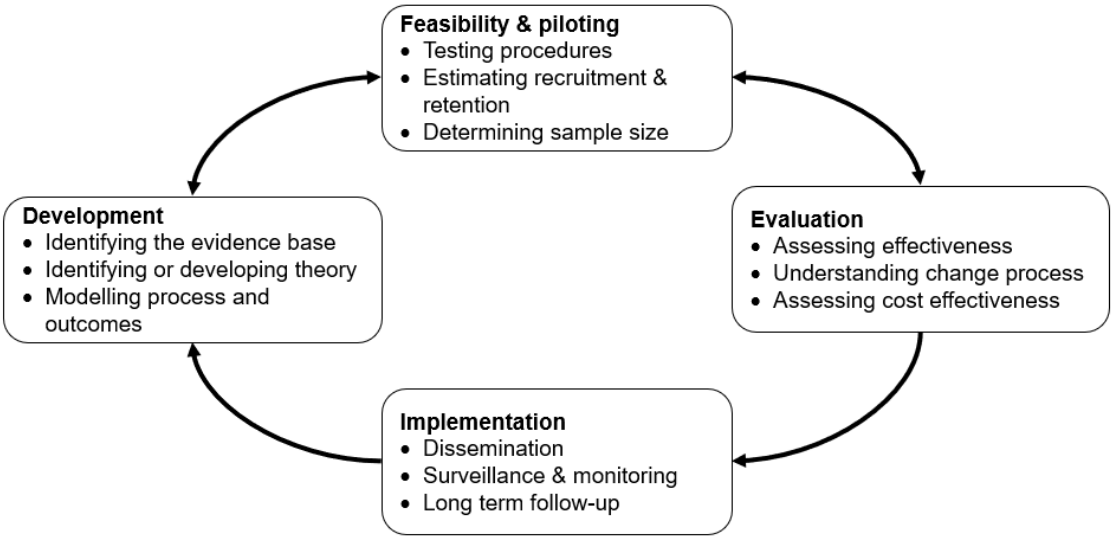

Figure 8: Key steps of the UK Medical Research Council guidance on developing and evaluating complex interventions [87]

The three steps involved in developing an intervention are identifying the evidence base, identifying/developing theory and modelling process and outcomes. These are briefly described here.

The first step to developing an intervention is *Identifying the evidence base*. This involves identifying what is already known about the topic of interest to inform the intervention development process. This could be achieved by identifying existing interventions, conducting a systematic review of published evidence and/or collecting primary data e.g., using qualitative focus groups and interviews to understand the evidence base. The next step, *Identifying or developing theory,* is key to understanding the theoretical rationale underpinning the intervention. This step could be achieved by drawing on existing published theory, e.g., behavioural theory or framework of theories. The third step, *Modelling process and outcomes*, involves intervention developers using a series of iterations to examine the intervention design and evaluation processes before a full-scale pilot and evaluation is planned. This modelling process can lead to refinements by identifying weaknesses in the intervention design or evaluation process.

Both the original 2000 [91] and updated 2008 [88] MRC guidance have been highly influential in supporting researchers, practitioners and decision makers in developing and evaluating complex interventions. However, the intervention development steps described above do not provide sufficient detail to inform the development of interventions, especially for researchers that are new to intervention development [89]. Further, since the publication of the updated MRC guidance in 2008, there have been considerable advances in approaches used to inform intervention development and evaluation, e.g., the use of theory, stakeholder engagement, how to approach complexity or take a multi-level perspective and the use of study designs other than randomised controlled trials. The MRC undertook a review of the evidence in 2018 and have produced a new draft version of the guidance, which was open for consultation from 22 March to 5 April 2019 [92]. Although the publication of this new updated MRC guidance has been delayed, actions to take during complex intervention development, which incorporates key recommendations from the new 2018 draft MRC guidance, have recently been published [89].

2.4 Guidance on how to develop complex interventions

Guidance on the key principles and actions to take during healthcare intervention development has been produced, based on published evidence and consensus among intervention developers and wider stakeholders [89]. The key principles and actions for intervention development are summarised below.

Key principles of healthcare intervention development

Intervention development is a dynamic, iterative and creative process, is open to change and requires consideration of future evaluation and implementation. Intervention development involves moving iteratively between overlapping steps, e.g., identifying relevant current evidence and supplementing it with stakeholder experiences and knowledge. The cyclical nature of intervention development allows continued refining of interventions based on

feedback to identify problems and implementing potential solutions. Being open to alternative possibilities ensures that interventions are feasible and acceptable and therefore more likely to be effective. Recognising factors that may impact the implementation and evaluation early in the intervention development phase will help to identify learning, resolve any uncertainties and optimise resource utilisation.

Key actions for healthcare intervention development

The key actions, that incorporate the above principles of intervention development, are listed in table 4. Ten actions are listed, although it is recognised that developers may not need to address all actions, nor might it be relevant to do so. The actions are not intended to be used sequentially, rather they are dynamic, overlapping and iterative and could be used in parallel. The actions taken should be tailored to the needs of the team involved in developing the intervention, the context and available resources. Table 4 shows the actions that guided intervention development in this thesis, by chapter, and whether the action was listed in the 2008 MRC guidance.

Several actions have been added to the 2008 MRC guidance to support intervention development, namely, understanding of the context, articulation of programme theory and involving stakeholders in the intervention development process.

Table 4: Actions considered for intervention development in this thesis

Action	Examples of things to consider for the action	Action listed in 2008 MRC guidance	Chapter				
			1 Background	3 Survey study	4 Realist review	5 Co-design study	6 Discussion
Plan the process	Understand the problem. Identify resources – time and funding Decide which approach to intervention development to take.	Yes	✓	✓	✓	✓	✓
Involve stakeholders	Work with service providers & users throughout intervention development. Develop a plan for public involvement. Identify ways to work with stakeholders. Use activities to understand the problem & generate ideas for the intervention.	No		✓	✓	✓	
Bring together a team	Include people with relevant expertise. Agree a process for making decisions about the intervention.	Yes	✓	✓	✓	✓	✓
Review published evidence	Review published evidence before intervention development. Identify existing interventions.	Yes	✓		✓		
Draw on existing theory	Identify existing theory or framework of theories at the start. More than one theory/framework can be drawn upon.	Yes			✓	✓	
Articulate programme theory	Develop programme theory – may draw on existing theory. Test and refine programme theory.	No			✓		
Undertake primary data collection	Use a range of research methods e.g., qualitative and quantitative methods.	Yes		✓	✓	✓	
Understand context	Understand context e.g., population, geography, social/cultural influences, funding, etc.	No	✓	✓	✓	✓	
Attend to future implementation	Understand barriers and facilitators to reaching the target population, future use of the intervention & sustainability.	Yes			✓	✓	✓
Design and refine	Generate ideas about intervention content, format & delivery with stakeholders. Refine intervention through iterations to assess acceptability and feasibility. Assess potential harms and unintended consequences. Consider early testing of the intervention.	Yes				✓	

✓ = Action taken during the development of the intervention for the PhD

An overview of understanding context, articulating programme theory and involving stakeholders, are provided below in sections 2.4.1, 2.4.2 and 2.4.3, respectively, and includes how they relate to intervention development.

A description of the approaches used to understand context, develop programme theories and engage stakeholders in this thesis are also provided briefly here in section 2.4.4, and elaborated on later in the chapter.

2.4.1 Understanding context

Context refers to "*any feature of the circumstances in which an intervention is conceived, developed, implemented and evaluated … that may interact with the intervention to produce variation in outcomes*" [93]. Features could include the immediate or wider organisational setting; geographical environment; demographic, epidemiological and socioeconomic characteristics of service users or providers; legal rules or ethical conventions; broader policies in which the intervention is embedded; cultural practices, beliefs and attitudes among service users and providers; historical or political factors affecting the intervention's acceptability; and how service users or providers interact with the intervention [93].

Complex interventions are strongly influenced by context. Awareness of the relationship between interventions and their contexts is key to understanding how and why interventions work or not, whether interventions can be adopted, scaled up or translated successfully from one context to another, why the impact of interventions may vary and how effects observed in one context can be generalised to other contexts. Recent years have seen a greater emphasis on strengthening the evidence on the relationships between interventions and contexts [93-96]. For example, in realist approaches to evidence synthesis, contexts influence intervention outcomes.

In this thesis, a realist review was undertaken to understand the contexts that influence healthcare practitioner delivery of self-management support to cancer survivors. More detail about realist approaches will be provided later in this chapter (section 2.5) and the results of the realist review will be presented in Chapter 4, where five contexts were identified as important for enabling healthcare practitioners to deliver self-management support to cancer survivors. The primary care context was further considered in this thesis when co-designing the intervention. Co-design will be introduced later in this chapter (section 2.7) and the results of the co-design study will be provided in Chapter 5.

2.4.2 Articulating programme theory

In this section, the definition and purpose of theory is provided first. The different types of theory used in social science is then described before programme theory is introduced.

Theory is defined as *"an ordered set of assertions about a generic behaviour or structure assumed to hold throughout a significantly broad range of specific instances"* [97]. Identifying or developing theory is a key step during intervention development [88]. Using theory can reduce the time needed for intervention development and optimise intervention design [98]. Theories are invaluable in explaining how, why and in what circumstances interventions work [99].

In some disciplines, such as social science, theories are categorised into three levels with varying application, scope, abstraction and complexity [98, 100]. At the most granular level there are 'programme' theories, which relate to specific interventions and are at a low level of abstraction and generalisability. This is followed by 'mid-range' theories, e.g., Normalisation Process Theory, which are broad enough to provide explanations across a range of contexts and thus more generalisable yet can still be tested and can be used to guide intervention development and evaluation. Finally, 'grand' theories, e.g., feminist theory, are at a high level of abstraction and generalisable across many contexts. Although

three levels of theory are described, boundaries between these levels are not always clear. For example, a programme theory providing an explanation of an intervention across multiple settings can be viewed as a mid-range theory. Similarly, frameworks that consolidate multiple theories can also be seen as a 'mid-range' theory as they aim to present an overarching view e.g., the TDF [100]. 'Mid-range' theories play a 'bridging role' between 'programme' and grand' theories, as shown in figure 9. Developing and ongoing iteration of programme theory has been recognised as a crucial factor for effective development of complex interventions, which is explored below.

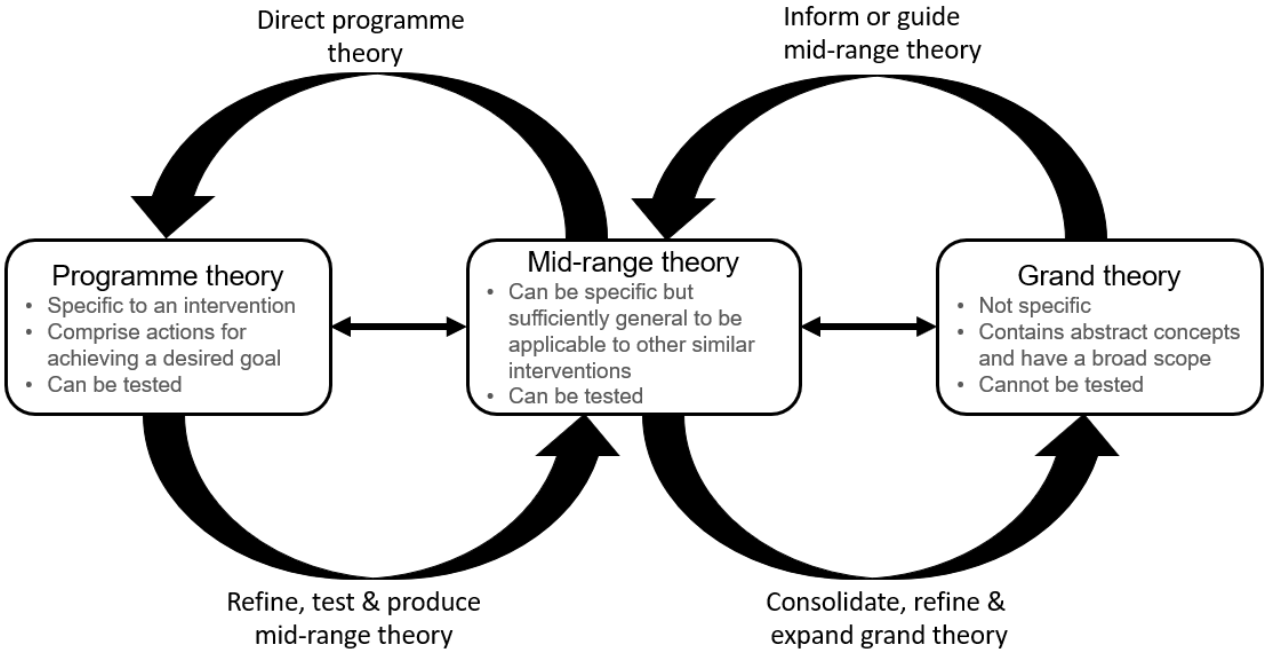

Figure 9: Bridging role of mid-range theory [14, 15]

The use of programme theory in realist approaches will be described later in this chapter (section 2.5.2). The development and refinement of five programme theories as part of the realist review will be described in detail in Chapter 4.

A programme theory describes *"the underlying assumptions about how an intervention is meant to work and what impacts it is expected to have"* [96]. Programme theory can be developed from various sources, e.g., published information about the intervention, mid-range or grand theory and stakeholder experience [98]. Programme theory articulates the

relationship between underlying mechanisms of the intervention, the contexts that are expected to influence those mechanisms and the intended or unintended outcomes that result from the interaction between the contexts and mechanisms [96, 101]. A programme theory is a combination of the key components, which are, the contexts, mechanisms and outcomes, and a narrative about the structures, behaviours, processes and contextual features needed to achieve the aims and objectives of an intervention [98]. Programme theories are dynamic and continuously updated and refined as understanding of the intervention deepens and as interventions are adapted and changed over time. Programme theory can help to inform transferability of the intervention across settings and produce evidence that is more applicable to decision-makers [92].

2.4.3 Involving stakeholders

Stakeholders "*are those who are targeted by the intervention or policy, involved in its development or delivery, or more broadly those whose personal or professional interests are affected i.e., who have a stake in the topic. This includes patients and members of the public as well as those linked in a professional capacity*" [92].

Involving multiple stakeholders from the beginning is important for understanding the key challenges, the wider context and system influences on intervention development. Identifying which stakeholders to involve will vary and will depend on the context, e.g., setting, and phase of the intervention, e.g., development or evaluation. Stakeholders can be involved in different ways, such as consultation or co-design [89]. Consultation may be appropriate when developers need to discuss and understand the problem or prioritise potential solutions to take forward in the intervention development. Other approaches for involving stakeholders, such as, co-design and co-production can help to facilitate partnerships where all stakeholders have equal say in decisions about intervention development. Both approaches attempt to identify a problem then generate ideas to address the problem. The difference between them is that in co-design the problem is defined and a solution is

identified, whereas in co-production an attempt is made to implement the solution [102]. Co-design and co-production approaches facilitate development of interventions that meet the needs of stakeholders, and hence are more likely to be effective and sustainable and supports a person-centred philosophy [103-105]. Stakeholders can be involved in different tasks, such as providing insights into the problems to address and potential solutions, developing and refining programme theory and facilitating understanding of the context. It is important for intervention developers to create an environment that allows open and collaborative discussions with stakeholders.

This thesis will describe the approaches used to involve stakeholders in the three empirical studies. Stakeholder involvement is listed here and will be described in detail in the chapters reporting on the studies:

- Chapter 3 – Cross-sectional study: Stakeholders included cancer survivors and healthcare practitioners, who informed and commented on the items used in the questionnaire designed for the study.
- Chapter 4 – Realist review: Cancer survivors and healthcare practitioners were consulted to comment on draft programme theories and supported prioritisation of programme theories for testing and refining in the review.
- Chapter 5 – Co-design study: Healthcare practitioners, cancer survivors and commissioners were involved in co-designing an intervention. This was done by identifying barriers and enablers to supporting cancer survivors to self-manage, generating solutions to address the barriers and designing an intervention to facilitate healthcare practitioners in general practices to deliver self-management support to older cancer survivors.

2.4.4 Approaches used in this thesis for the intervention development

Many approaches may be used to guide intervention development. These include partnership approaches e.g., co-design, and theory and evidence-based approaches, such as aiming to change behaviour using the TDF. A combination of approaches may also be used to build on the strengths of each approach. No one approach has been shown to be better than another [89].

In this thesis, the steps described for intervention development in the 2008 updated MRC guidance [88] were combined with the three additional actions described in the guidance on how to develop complex interventions [89], namely, consideration of the context, developing programme theory and involving stakeholders in the intervention development phase [92].

The approaches selected to support the intervention development in this thesis are described here. A realist approach was used to develop programme theory to understand the influence of context on intervention outcomes. A co-design approach was used in the development of the intervention. The planned intervention will aim to change the behaviour of healthcare practitioners, which led to the use of the TDF. The TDF guided programme theory development in the realist review and was the underpinning theory that informed the design of the intervention. Realist approaches and the TDF both pay explicit attention to the importance of context for understanding effectiveness of interventions and determining the individual, social, organisational and wider system-level influences on behaviour.

The realist and co-design approaches and the underpinning theory using the TDF are described in detail below and a rationale for their selection is provided.

2.5 Realist approaches

2.5.1 Realist philosophy

Realism, along with positivism and constructivism form the three broad schools of philosophy. Each make different assumptions about the nature of the world (ontology) and nature of knowledge (epistemology). These assumptions, which are summarised in table 5, have implications for how data are presented, analysed and evaluated [106]. Realism sits somewhere between positivism and constructivism.

Table 5: Summary of the ontological and epistemological assumptions when conducting research

	Positivism	**Realism**	**Constructivism**
Ontology The nature of reality	Reality exists independently of peoples' interpretation and is governed by natural laws.	Reality is assumed to exist but cannot be fully understood.	No single reality exists. Reality is constructed in peoples' minds.
Epistemology How reality is known	Facts about reality are identified through observation and theory. Only things that can be observed are considered a valid source of knowledge.	Similar to constructivist epistemology	All knowledge is socially and individually constructed and interpreted. Whether reality exists or not is not clear. Facts are accepted to be true.
Role of the researcher	To identify and report observable facts.	To explain how and why interventions, programmes or policies cause their various outcomes in different sets of circumstances.	To identify and report the meanings and interpretations that people give to experiences.
Study designs	Quantitative e.g., randomised controlled trials	Both quantitative and qualitative designs are used.	Qualitative

Key terms used in realist philosophy include: mind-independent reality, generative causation, ontological depth and retroduction [107]. These are briefly explained below:

- Mind-independent reality relates to the idea that the world exists independent of our knowledge of it. Our knowledge of reality is partial and prone to fallibility.

- Generative causation relates to the underpinning hidden mechanisms that generate (cause) outcomes. This contrasts with successionist causation, which is based on the idea of observing the correlation between empirical events to infer causation.
- Ontological dept refers to the idea that reality is stratified in layers. This suggests that we need to look at multiple 'levels' to understand why something has manifested in the way it has, e.g., individual, intraindividual, community and societal levels. The iceberg metaphor is often used to explain realist ontological dept and illustrates the existence of mechanisms in the deeper layers of reality.
- Retroduction is the activity of uncovering hidden mechanisms in interventions.

Realism is a methodological approach that uses available research methods and techniques to understand 'what is it about this intervention or programme that works for whom and in what circumstances?'. This is done by trying to establish a causal relationship to understand the connection between the contexts and outcomes [108].

2.5.2 Scientific realism

The realist review, reported in Chapter 4 of this thesis, used scientific realism, which is described below.

Scientific realism has many names, such as empirical realism, emergent realism, analytic realism and middle-range realism [109] and was first proposed in 1989 by Pawson [110]. For the purpose of this thesis, it will be referred to as scientific realism. Scientific realism was developed to understand complex interventions, such as healthcare and policy interventions to understand why some interventions may work in some contexts and not in others [96].

The hallmark of scientific realism is understanding the causal relationships between these different features of complex interventions. Scientific realism uses programme theory to

explore how context interacts with various mechanisms to produce outcomes. *A programme theory* describes the theoretical relationship between contexts, mechanisms and outcomes, and is represented as: *context* + *mechanism* = *outcome* [111].

The *context* refers to any factors that may influence programme outcomes such as healthcare setting, incentives, and practitioner knowledge [107]. *Mechanisms* comprise two parts; the resources offered by an intervention or programme and the ways these resources might change the reasoning of people [112]. Examples of resources include information or advice and examples of reasoning include trust, motivation or engagement [107]. *Outcomes* are the positive or negative effects of the intervention or programme, which are based on the interaction between the context and mechanism. Some examples of outcomes include decision making, resilience, health outcomes and social interactions [107]. Once developed, programme theories are tested against evidence to explain "How does it work?", "Why does it work?", "For whom does it work?" and "In what circumstances does it work?"[96]. Testing is an iterative process of abductive reasoning which involves examining the evidence to develop ideas [113], together with retroduction, a process of unearthing the causal links between contexts, mechanisms and outcomes [107]. The resultant refined theory, if sufficiently broad to allow transferability or portability to similar interventions or programmes [114], is termed a 'middle-range' or 'mid-range' theory. This mid-range theory serves to explain how interventions or programmes work and can be used to design and implement innovative interventions within complex environments [107]. Stakeholder engagement throughout the realist process is encouraged to ensure inclusion of multiple perspectives [111].

2.5.3 Realist reviews

A realist review (or realist synthesis) mainly uses secondary data and is a form of systematic literature review. There are several differences between a realist review and a conventional systematic review [108, 115], summarised in table 6.

Table 6: Methodological differences between conventional systematic reviews and realist reviews

Conventional systematic review	**Realist review**
1. Identify the review question	1. Clarify scope of the review: identify the review question, refine the purpose of the review, articulate key candidate theories to be explored
2. Search for primary studies using clear pre-defined inclusion and exclusion criteria	2. Search for relevant evidence, refining inclusion criteria in the light of emerging data
3. Appraise the quality of studies using a pre-defined and validated critical appraisal checklist, considering relevance to the research question and methodological rigour	3. Appraise the 'quality' of studies using judgement to consider relevance and rigour from a 'fitness for purpose' perspective
4. Extract standard items of data from all primary studies using a template or matrix	4. Extract different data from different studies using a range of tools (e.g., Microsoft Excel, NVivo) in an iterative fashion
5. Synthesise data to obtain effect sizes and confidence intervals and/or transferable themes from qualitative studies	5. Synthesise data to achieve refinement of programme theory, that is, to determine what works for whom, how and under what circumstances
6. Make recommendations, especially with reference to whether the findings are definitive or if further research is needed	6. Make recommendations, especially with reference to contextual issues for particular policy-makers at particular times
7. Disseminate the findings and evaluate the extent to which practitioners' behaviour changes in a particular direction	7. Disseminate the findings and evaluate the extent to which existing programmes are adjusted to take account of elements of programme theory revealed by the review

A realist review is an interpretative theory-driven approach to evidence synthesis, involving the identification and testing of theory. Theories are initially built using multiple sources of evidence such as published studies, policy documents, grey literature, formal theories or stakeholder input [96]. These theories are then tested against existing research. Systematic reviews, on the other hand, are method driven. Method driven reviews give priority to experimental and quasi-experimental design, such as, randomised controlled trials. Systematic reviews are good for understanding whether interventions work or not. However, they have been argued to be less informative in explaining why some interventions work and others don't, or in what circumstances they are likely to work, or what needs to be in place to maximise their success [108].

A key feature that distinguishes realist reviews from conventional systematic reviews is that the focus of the realist review is the programme theory and not the entire intervention or programme. A wide range of study designs can be included in a realist review, such as, qualitative, quantitative, and mixed methods.

Justification for selecting a realist review in this thesis, for evidence synthesis related to self-management support interventions in cancer survivors

Systematic reviews on self-management support in cancer survivors have failed to identify the key components for their successful implementation [77, 116]. Diversity of interventions and poor study designs were quoted as being key limitations [77, 79, 81, 116]. Improved intervention designs using theory-driven approaches are needed to facilitate the translation of self-management support interventions into routine practice [116]. Realist approaches seek to make sense of interventions by identifying the key contexts, mechanisms and outcomes involved while considering the heterogenous nature of interventions or the setting in which they are delivered [96, 117]. A realist review was therefore used in this thesis to synthesise the available evidence and is reported in Chapter 4.

Contribution of this thesis to advance the methodological approach to realist reviews

Despite the growing popularity of scientific realism, there is a lack of detailed instruction for developing a realist review protocol or for conducting a realist inquiry [107]. This is both an advantage and a challenge. Lack of prescriptive instructions allows researchers to adapt novel approaches to their realist inquiry but could also result in a realist inquiry that produces inadequate causal explanations for what works for who, why, and in what circumstances.

As the popularity of using realist approaches for healthcare synthesis grows, researchers are seeking novel ways of incorporating other published methodologies into their work to provide structure for the evidence synthesis. For example, using formal theory from disciplines such

as sociology and behavioural science has emerged as a strategy to providing a framework for generating realist programme theories [118].

The realist review reported in Chapter 4 used the TDF to guide programme theory development and refinement. The two approaches complement each other. The TDF provided a theoretical lens through which to view “contexts”, such as social and environmental factors, and “mechanisms”, such as cognitive and affective factors and how they influence behavioural “outcomes.” The realist approach, on the other hand, allowed interrogation of the relationships between the different contexts, mechanisms and outcomes.

The TDF is introduced in the section below, which describes how it was used in the realist review in this thesis.

2.6 Theoretical Domains Framework (TDF)

The TDF is widely used in healthcare to identify barriers and enablers to healthcare practitioner behaviour change [87] [119]. The TDF is a synthesis of 128 constructs from 33 theories of behaviour change clustered into 14 domains: knowledge; skills; social/professional role and identity; beliefs about capabilities; optimism; reinforcement; intentions; goals; memory, attention and decision processes; environmental context and resources; social influences; emotion; and behavioural regulation [87]. A key advantage of the TDF is that its domains have been mapped to behaviour change techniques (BCTs) which are the active ingredients of interventions. This mapping facilitates selection of the most effective components when designing theory-based interventions to change practitioner behaviour [120]. This can be achieved using the Theory and Techniques Tool (https://theoryandtechniquetool.humanbehaviourchange.org), an online interactive resource that provides information about the links between the TDF domains and associated behaviour change techniques. The tool was developed from published evidence, expert

consensus and triangulation studies. The Theory and Techniques Tool was used to select the behaviour change techniques for developing the intervention to address barriers to facilitating practitioners in general practice to provide self-management support to older cancer survivors, which is described in Chapter 5.

Theoretical frameworks should explicitly be used in the development of self-management support interventions in the cancer stetting [116]. They help to understand the process of change required and, in the identification, and selection of effective intervention components. A broad framework of established theories can also help to develop realist programme theories [118]. The framework used may include concepts drawn from existing theories, which collectively provide an explanatory framework and structure within which to develop an initial set of programme theories. The TDF is valuable for developing programme theories for complex interventions, such as self-management support. Further, the TDF can provide a structure within which to situate more detailed analysis [118]. The TDF was used to support the development of programme theory and facilitate analysis of data in the realist review undertaken in this PhD. The potential benefits and challenges of using the TDF in a realist review are outlined below.

2.6.1 Potential benefits of combining the TDF with a realist approach

Using the TDF could provide realist researchers with a structured approach to building programme theory. There are no guidelines or criteria to assess suitability of formal theory for building realist programme theory. Using the TDF may overcome this issue as it ensures the use of a wide range of theories – providing justification for use of appropriate formal theories and limits the likelihood of using inappropriate formal theories.

There is notable overlap between the realist approach and the TDF. Both make explicit use of theory; acknowledge the influence of context at multiple levels such as individual,

interpersonal, institutional and infrastructural; and provide a method for progressing from a theory-based investigation to intervention development.

2.6.2 Potential challenges of combining the TDF and realist approaches

There is a flexible approach to the use and application of both the TDF and realist research. The lack of step-by-step guidance coupled with the need for training and experience in the use of the two approaches could result in a lack of appropriate interpretation of the evidence, such as, lack of understanding of the TDF domains could lead to mapping the evidence to the wrong domain or inappropriately mapping evidence as 'context', when it is a 'mechanism'. This could lead to developing misleading or superficial explanations of what works, for who, why, how and in what circumstances. Generating evidence that is of poor quality cannot be applied further to policy or intervention development and implementation.

The PhD supervisory team had extensive working knowledge of the TDF and provided guidance for application of the TDF domains during programme theory development and refinement. Scientific realism was new to the PhD supervisory team. KK therefore attended training on realist methods and had the support of a realist mentor during the early stages of planning the realist review. In addition, KK had the opportunity to share preliminary findings of the realist review and share her experience of undertaking a realist review at a training conference aimed at PhD students new to using realist approaches.

The TDF can be used at various stages of the realist process, such as when mapping empirical evidence, developing programme theory and informing intervention development.

Using the TDF could result in the generation of abundant programme theories as multiple theories could be generated across the 14 TDF domains. It may not be possible to test all due to resource limitations. To overcome this challenge, stakeholder feedback was sought to

help prioritise the programme theories for testing in the realist review in this PhD, which is described in Chapter 4.

Further, using an *a priori* framework may lead to a deductive approach to evidence analysis, which could lead to inadvertent omission of relevant contexts or causative mechanisms.

The use of technical jargon in both the TDF and realist approaches could limit accessibility or lead to misinterpretation, e.g., misinterpretation of TDF domains could lead to mapping of behavioural determinants to an inappropriate domain or lack of understanding of the difference between context and mechanism could lead to development of mid-range theory that has limited applicability and generalisability. The experience of using the TDF in the realist review will be discussed in Chapter 6 of this thesis.

In this thesis, a realist approach will be combined with a behavioural framework, the TDF, to understand context and articulate programme theory. The TDF will also be used to inform the selection of effective behaviour change techniques during the intervention development. The involvement of stakeholders in the realist review has been described already (section 2.4.3). A further approach used to involve stakeholders in this PhD is co-design. The next section describes the principles of co-design and the process used for the final empirical study in this thesis, which will be reported in Chapter 5.

2.7 Co-design

In the last decade there has been a growth in the use of co-design in health care settings to improve the quality of or develop new services, technology and community-based healthcare [104]. The co-design approach follows a set of key principles [104, 121], listed below:

- Sharing of power – the research is jointly owned and people work together to achieve a shared understanding.

- Including all perspectives and skills – to ensure the research team includes all the people who can contribute.
- Respecting and valuing knowledge of all – all people working together on the research are of equal importance.
- Reciprocity – everyone benefits from working together.
- Building on maintaining relationships – an emphasis on relationships is key to sharing power.

These principles include the involvement of end users and other relevant stakeholders in the co-design process, joint ownership of the co-design process by research teams and participants, where all perspectives and skills are included and all knowledge is equally respected and valued [122]. Co-design produces solutions based on the experience of service users and providers, resulting in a 'product' that meets the needs of all stakeholders. Services designed using this approach are more likely to be acceptable to and adopted and sustained by service users and providers [123].

Successful co-design requires collaboration between multiple stakeholders, e.g., patients, carers, researchers, practitioners, managers and policy-makers, and is driven by productive conversations and meaningful activity [104, 124]. This requires an understanding of the roles and contexts of all stakeholders. What motivates researchers will be different from what motivates practitioners and patients. The connection and rapport between the relevant stakeholders are also key to collaboration. The qualities that facilitate researchers to engage in meaningful co-design include being open, being comfortable in the setting where the co-design will take place, being good communicators, being flexible and adaptable to changing situations, and being able to manage conflict and be creative. Researchers need to balance this against maintaining the standards for good quality research. Qualities of non-academic stakeholders include being patient with researchers and commitment to engage in the

process until completion. Some challenges of engaging in the co-design process include the time and effort needed to build and maintain genuine collaboration, the need for resources to undertake co-design and practical challenges, such as, if there is a change in the research team facilitating the co-design process, the established connections with co-design participants could be broken [124].

There are numerous processes that could be used to operationalise the co-design approach, e.g., the Person-Based Approach [125], the Double Diamond process [126], Stanford Design Thinking Process [127] and Experience-based Co-design (EBCD) [128]. The approach to knowledge is shared by these processes, where all types of knowledge is valued, the gradual growth of knowledge, acknowledgement of the complexity and context in which the process take place and meaningful participation of stakeholders [124].

Justification for using a co-design approach in this thesis

A co-designed intervention has the potential to be relevant and acceptable to healthcare practitioners and older cancer survivors and to improve the quality of care provided by primary care teams in the NHS in England. Working with healthcare practitioners and cancer survivors will likely provide fresh insights and bring new ideas for designing an intervention that meets the unique self-management needs of the local population. KK had experience of cancer care in secondary care, so it was important to get the first-hand perspectives of primary care teams and older cancer survivors to ensure that the intervention designed would be beneficial to patients and deliverable in primary care. Given the pressures faced by primary care teams currently, it was important to work with healthcare practitioners and cancer survivors in a meaningful way to embed the intervention in routine care as far as possible. The experiences of using a co-design approach for intervention development will be discussed in Chapter 6 of this thesis.

The Stanford Design Thinking process will be used for this PhD to support co-design of a self-management support intervention. The 5-step Stanford Design Thinking process will be described in detail in Chapter 5. The rationale for selecting this process was pragmatic. One member of the research team (JT) had expertise in the use of the process [129] and provided guidance during the co-design workshops (Chapter 5). This process has been used in co-designing self-management interventions in other healthcare settings, e.g., heart failure [105] and chronic obstructive pulmonary disease [130].

2.8 Chapter summary

This chapter introduced the approaches applied in the empirical studies in this thesis including their justification. This chapter has provided an overview of the key steps for intervention development based on the UK MRC guidance published in 2008 [88] and more recent guidelines on how to develop complex healthcare interventions [89]. The recent guidance for developing complex healthcare interventions is based on advancement in the field, specifically the need for consideration of context, developing programme theory and involving stakeholders. The methodological approach selected for this PhD, scientific realism, and in particular realist review, incorporates all three additional steps described in the guidance on how to develop complex interventions, and will be reported in Chapter 4. Further, a behavioural framework, the TDF, has been embedded into the realist review to provide structure for programme theory development and further theoretical underpinning of the intervention. The TDF will further allow identification of multi-level barriers and enablers to practitioner behaviour change and selection of effective components and linked behaviour change techniques when designing the theory-based self-management support intervention, reported in Chapter 5. Findings from the realist review (Chapter 4) will feed into the co-design study (Chapter 5) with key stakeholders to inform the design of a service in primary care for delivering self-management support to older people living with long-term consequences of anticancer treatment.

This chapter also introduced a tentative logic model to visually represent the contribution of each chapter during the intervention development process. The contribution made by Chapter 1 was included in the logic model, which will be further populated in subsequent chapters and are included in the chapter summaries.

Chapter 1 discussed the existing evidence base concerning the nature and size of unmet needs of adult cancer survivors and the potential role of self-management support in this population. However, there is a knowledge gap in terms of the specific supportive care needs of older people after they have completed anticancer treatment. There are likely to be unmet needs related to cancer alongside multimorbidity and functional decline in older people. A better understanding of the unmet needs of older cancer survivors post cancer treatment is required in order to understand the nature and size of their unmet needs and if they are being adequately supported by current service provision.

There is therefore a need to conduct empirical research exploring the experiences of older cancer survivors after completing anticancer treatment and if the current support offered is adequate. The cross-sectional study to estimate the prevalence of side effects after completing anticancer treatment will be presented in Chapter 3. The results of Chapter 3 will inform the development of a self-management support service that is fit for their needs and in a setting that is easily accessible and acceptable to older cancer survivors.

Chapter 3 Prevalence of long-term consequences of anticancer treatment and satisfaction with care in older cancer survivors

3.1 Introduction

Chapter 1 detailed the impact of the long-term and late consequences of cancer and its treatment in adult cancer survivors. Chapter 1 further elaborated on the specific issues faced by older adults, which are compounded by the physical and cognitive decline associated with ageing and the presence of multiple long-term conditions. The supportive care needs of older people just before starting and during anticancer treatment are understood. However, the evidence for the supportive care needs of older cancer survivors after completing anticancer treatment is limited. Chapter 1 identified a gap in the evidence related to the size and scope of unmet needs of older adults post anticancer treatment. Furthermore, it is important to establish whether existing services are adequate for supporting the needs of older cancer survivors. Both are crucial for informing the development of a self-management support intervention in this population. This chapter describes a cross-sectional study to explore the prevalence of long-term anticancer treatment-related side effects and satisfaction with current cancer care in older people after completing anticancer treatment. A cross-sectional study design was selected as it provided a useful method for estimating prevalence of outcomes, related to consequences of treatment and care satisfaction, for the purpose of identifying perceived gaps in cancer survivorship care to inform intervention development.

Before the study is described, a background is provided on advancements made in anticancer treatment and their impact on quality of life of older cancer survivors.

3.2 Background to the study

As introduced in Chapter 1, anticancer treatment refers to drug treatment which includes cytotoxic chemotherapy, hormone therapy, targeted therapy and immunotherapy. Over the

past decade, there has been an exponential development and use of anticancer treatment, particularly targeted therapy and immunotherapy, in routine cancer care. There have also been innovations in combining different types of anticancer treatment to improve patient outcomes [131]. The newer targeted therapy and immunotherapy, despite offering more specificity and efficacy than cytotoxic chemotherapy and hormonal therapy, can cause severe and unpredictable long-term and late side effects [131, 132]. Mounting evidence on the use of anticancer treatment in older people suggests that although efficacy is similar to that in younger adults, older people are at increased risk of anticancer treatment-related side effects [11]. This is likely related to a decline in the body's drug handling processes and greater likelihood of the presence of other long-term conditions. Older people may also have cognitive and functional decline and fewer social interactions or networks which may affect how they cope with anticancer treatment [61]. Living with cancer and other comorbidities also presents an increased risk of interactions between treatment for comorbidities and anticancer treatment [9]. Additionally, living with comorbidities is associated with higher mortality, a higher disability burden, poorer health outcomes, more frequent health service use and poorer quality of life in older people with cancer compared to those without cancer [54, 133-136].

Unmet physical, emotional and practical needs have been reported in a third of American cancer survivors [137], about two-thirds of survivors across the Asia-Pacific region [138] and in over three-quarters of Canadian cancer survivors [139]. In 2005, a UK longitudinal cohort study of 1,850 adult cancer survivors reported that 19% had unmet needs arising from cancer treatment-related physical problems. It also captured a range of unmet needs related to psychosocial problems with the most frequent being emotional wellbeing, reported by 26% [140]. In 2012, a pilot survey of the quality of life of adult cancer survivors with breast cancer, colorectal cancer, prostate cancer and non-Hodgkin's lymphoma was conducted in England [141, 142]. The survey found that the presence of comorbidities, disease status, age and physical activity influenced the overall quality of life. Older participants were less positive

about mobility and undertaking their usual activities or domestic chores. One in five survey participants reported having other illnesses, e.g., hypertension, arthritis, osteoporosis, diabetes, long-term back pain, depression and anxiety. Those with other long-term conditions had poorer quality of life than those without long-term conditions. Some participants indicated that cancer treatment had worsened symptoms of other illnesses or that they found it difficult to distinguish between symptoms caused by cancer or its treatment or other illnesses [142]. Participants further reported that they were not prepared for the long-term physical side effects related to cancer and its treatment, such as, urinary or bowel incontinence, fatigue, peripheral neuropathy, and pain. Nor were they prepared for the psychological side effects, such as, fear of cancer recurrence, altered body image, depression and anxiety, of cancer and its treatment, which sometimes caused social problems. Participants added that there was lack of information, support or signposting for support services and other coping or self-management strategies. Survey participants attending follow-up clinics in secondary care described 'rushed' appointments or 'dismissive' attitudes of healthcare practitioners towards ongoing problems related to treatment. Some further commented on the lack of input from their general practitioner or other primary care practitioners. As a result, participants described feeling isolated, vulnerable and 'cut adrift' by the healthcare system after completing cancer treatment. This led some to rely on family and friends for help and support. However, participants reported that family members themselves needed emotional support to come to terms with cancer in loved ones and practical advice.

Empowering older cancer survivors to recognise and manage the long-term consequences of anticancer treatment could facilitate better adjustment to life after treatment and minimise the feeling of abandonment by the healthcare system after initial anticancer treatment [143]. The literature describing quality of life of adult cancer survivors is valuable in understanding the experiences and needs of people following cancer treatment. However, the literature does not provide sufficient details of the nature and extent of the specific needs of older people ≥ 65 years following cancer treatment. In particular, the evidence for the long-term

impact of anticancer treatment in older people is unclear. This study focused on breast, prostate and colorectal cancers, which are common in older people and have high survival rates.

3.3 Aim

3.3.1 Primary aim

The primary aim of this study was to estimate the prevalence of anticancer treatment related side effects after completing initial anticancer treatment in older cancer survivors diagnosed with breast, colorectal or prostate cancers in the last two years.

3.3.2 Secondary aims

The secondary aims were to assess:

- the extent to which cancer services in the NHS in England are supporting older people to manage long-term anticancer treatment related side effects, and
- older people's overall satisfaction with their cancer care.

3.4 Ethics approval

The study was confirmed as a service evaluation by the University of East Anglia Faculty of Medicine and Health Sciences Research Ethics Committee (reference 201819 – 008). The study was approved by the Research and Development/Audit/Governance departments across all participating sites:

- Norfolk and Norwich University Hospitals NHS Foundation Trust (Research and Development department reference: 201819 (177-12-18) and Audit department reference: SMW/mj)
- North West Anglia NHS Foundation Trust – Peterborough City Hospital and Hinchingbrooke Hospital sites (reference: HP/2018/CaSES)
- West Suffolk NHS Foundation Trust (email approval on 29/01/2019)

- East Suffolk and North Essex NHS Foundation Trust – Colchester Hospital (reference: 19/005)
- Guy's and St Thomas' NHS Foundation Trust – Guy's Hospital site (reference: 9327)

The study protocol is provided in Appendix A and ethical and site approval letters or emails are provided in Appendix B.

3.5 Methods

3.5.1 Study design and eligibility criteria

Participants were recruited to take part in a survey from six NHS hospitals. Patients were eligible if they were 65 years old or more, diagnosed with breast, colorectal or prostate cancers, had completed initial anticancer treatment in the last two years, and attended the hospital's cancer outpatient follow-up clinic. We excluded patients if their clinical care team deemed them unable to give informed consent, they had a mental health problem that could be exacerbated by participation or they were too ill to engage in the survey. Patients were also excluded if they did not speak, read or understand English.

3.5.2 Questionnaire development

Assessment of existing questionnaires

Existing questionnaires assessing the impact of cancer and its treatment on adult cancer survivors were deemed unsuitable for use in this study for several reasons. Firstly, validated questionnaires currently available for people with cancer, e.g., European Organisation for Research and Treatment of Cancer core questionnaire (EORTC QLQ-C30) [144] and Functional Assessment of Cancer Therapy – General (FACT-G) [145] were designed to assess the acute impact of cancer and cancer treatment, rather than the long-term consequences of cancer treatment which is the topic of this study. Hence the existing questionnaires were considered inadequate to assess the supportive needs of cancer

survivors living with long-term physical and psychosocial problems related to anticancer treatment.

Secondly, although many questionnaires have been developed specifically for adult cancer survivors who have completed treatment, e.g., Cancer Problems in Living Scale (CPILS) [146], Quality of Life in Adult Cancer Survivors (QLACS) [147], Quality of Life Cancer Survivors (QoL-CS) [148], and Impact of Cancer (IOC/IOCv2) [149-151], they have mainly been used in long-term cancer survivors who were living five or more years post diagnosis [152]. Cancer survival can be categorised into three groups: shorter term survival which includes people dying within a year of diagnosis; intermediate survival which includes people living for more than a year but less likely to be alive beyond 5 years; and long-term survival which includes people living 5 years or more after diagnosis [153]. Cancer survivors across these categories have different experiences and support needs [153]. Questionnaires designed to assess quality of life of cancer survivors living five years or more after a diagnosis may therefore be inadequate to capture the supportive care needs and experiences of those living beyond cancer for under five years. The existing adult cancer survivor questionnaires were therefore considered unsuitable for capturing their experiences.

Finally, there are no questionnaires which assess the experiences of older cancer survivors who have completed cancer treatment. The European Organisation for Research and Treatment of Cancer has developed a questionnaire to assess quality of life of older people, aged >70 years, with cancer, the QLQ-ELD14 [154], designed to be used in conjunction with the QLC-C30 [144]. Both the QLQ-ELD14 and QLC-C30 are useful for assessing generic issues affecting older people with cancer and have a strong focus on psychosocial issues. However, they pay little attention to assessing the long-term physical effects of cancer and its treatment [154, 155]. Furthermore, there are no existing questionnaires specifically focused on assessing the impact of anticancer treatment on older cancer survivors. A

bespoke questionnaire was therefore developed to meet the aims of this study, which is described below.

Tools used to assess quality of life are useful for identifying peoples' concerns by assessing factors that affect their quality of life. But quality of life tools do not assess what additional support people need to address their concerns. For example, a quality of life tool may assess a person's physical capability but it will not identify if the person has a need for physical assistance. Supportive care needs assessment tools identify specific assistance cancer survivors require to address their concerns and allow delivery of care to meet their needs. Currently there is limited guidance to inform the use of specific supportive care needs assessment tools in cancer survivors. A recent rapid review to assess the quality and implementation of needs assessment tools in cancer survivors [156] identified three tools commonly used in the post-treatment setting for adult cancer survivors: Survivors Unmet Needs Survey (SUNS) [157], the Short Form Survivor Unmet Needs Survey (SF-SUNS) [158] and Cancer Survivors Unmet Needs (CaSUN) [159]. However, none of the tools identified in the rapid review were designed specifically for older cancer survivors. Further, existing tools do not identify the needs of cancer survivors to manage side effects related to anticancer treatment. A bespoke questionnaire was therefore developed for this study. The conceptual model used to generate the questionnaire items is summarised below before providing a description of the questionnaire items.

Conceptual model used for item generation

The questionnaire for the present study was informed by the conceptual model developed from the 2012 English pilot survey data of the quality of life of adult cancer survivors with breast cancer, colorectal cancer, prostate cancer and non-Hodgkin's lymphoma [142]. Sixty-one per cent of respondents were aged 65 years or more. The model delineates three core dimensions: physical/psychological recovery, confidence in the future and ability to self-manage consequences of cancer and its treatment (figure 10). The model includes six

factors that negatively impact outcomes: emotional impact, quality of life, co-morbidities, treatment related side effects, social/financial difficulties and preparation for impact of cancer and cancer treatment. The model also has four professional-led and two survivor-led factors that supported recovery. The professional related factors that supported patient recovery were co-ordination of hospital treatment, preparation for anticipated problems or side effects, support to develop self-management strategies and aftercare services. Patient related factors that supported cancer survivor recovery were self-learning or learning from the experiences of other cancer survivors.

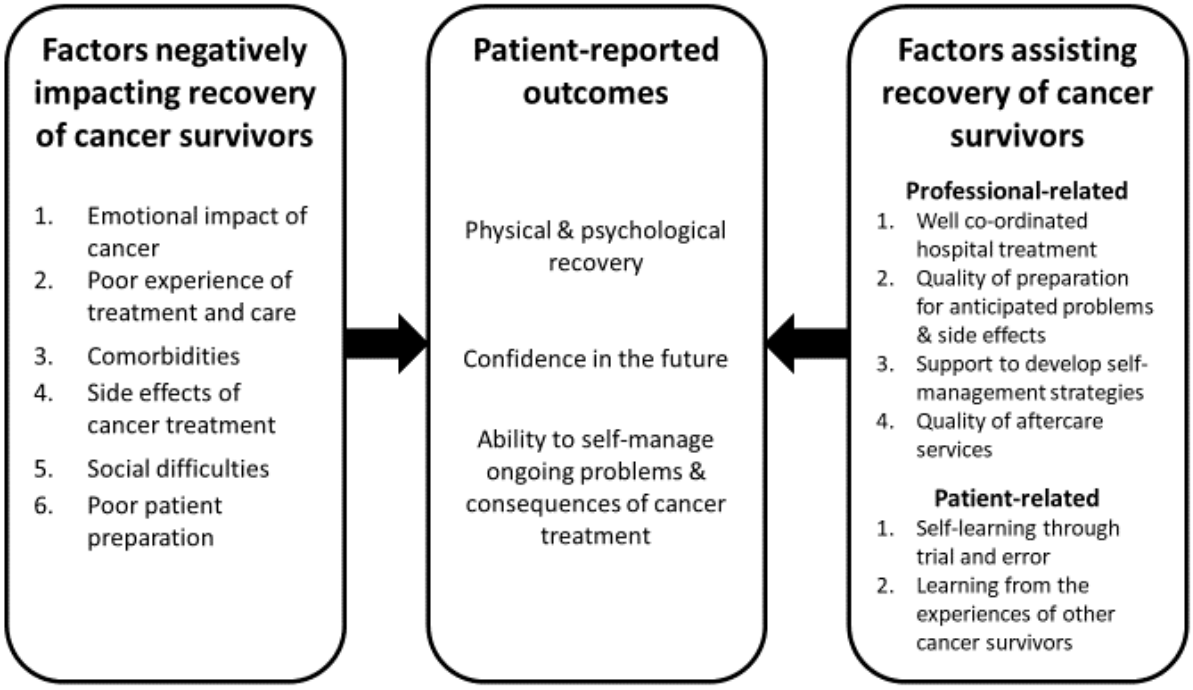

Figure 10: Factors impacting upon quality of life of cancer survivors [142]

The conceptual model of health and wellbeing in UK cancer survivors (figure 10) [142], together with an existing survey of survivors of prostate cancer [160] and stakeholder consultation were used to develop the draft questionnaire items in paper format.

Face and content validity

The paper version of the draft questionnaire was distributed to two cancer groups located in East of England and South East London, UK. The groups included cancer survivors and

healthcare practitioners working with cancer patients. Members of the groups reviewed the draft questionnaire and provided free-text feedback on the content and phrasing. This ensured that important content was included in the questionnaire. Feedback was reviewed and items were iteratively refined accordingly.

Pilot testing

The questionnaire was converted into an online format and then administered at one UK ambulatory anticancer treatment infusion centre (Appendix C) over a 2-week period in November and December 2018. The paper recruitment log, which included brief questions about demographic variables and survey administration details was also piloted. Researchers at the pilot site tested the useability of the recruitment log and administration of the online questionnaire. Piloting also tested whether questionnaire items were understood by patients and were not ambiguous. Of the 80 eligible patients approached by researchers, the questionnaire was piloted in 37 patients, giving a response rate of 46%. The median (IQR) age was 73 years (69, 78) and 57% were female. About 42% of patients in the pilot were diagnosed with breast cancer, 33% with bowel cancer and 25% with prostate cancer. An error involving a wrong response option for one item in section A (corresponding to question 2.7 in the paper questionnaire) was identified during piloting. The option ‘strongly disagree’ was available as an option in error, instead of ‘always’, this was corrected in the online questionnaire before the final version of the online questionnaire was distributed to the six participating sites. No further changes were made to the questionnaire after piloting; however, results of the pilot were excluded in the final analysis as some respondents were patients still receiving initial anticancer treatment.

Final questionnaire items

The different sections of the 23-item questionnaire are described here, and a copy of the paper version of the questionnaire can be found in the study protocol in Appendix A and the online version can be found in Appendix C:

Anticancer treatment related consequences:

Anticancer treatment related consequences were measured across seven domains: physical health, emotional wellbeing, social life, relationships with family and friends, ability to deal with problems related to cancer or anticancer treatment, ability to manage other long-term conditions and ability to adjust to life after anticancer treatment. Each of these domains comprised several items and invited participants to score their experiences of anticancer treatment related consequences in the last month. Scoring was on a 5-point scale ranging from 'never' (score=0) to 'always' (score=4) with higher scores indicating more negative impact. A negative impact was defined as participants selecting 'rarely' (score 1), 'sometimes' (score 2), 'often' (score 3) or 'always' (score 4).

Support to manage anticancer treatment related consequences:

For participants experiencing anticancer treatment related consequences, their views about support from hospital healthcare practitioners to manage consequences was measured. Scoring was on a 5-point Likert scale ranging from 'strongly agree' (score=1) to 'strongly disagree' (score=5) with higher scores indicating lesser agreement that support needs were met, in the previous month.

Satisfaction with care:

Participants' overall satisfaction with support and care during and after completing anticancer treatment were measured. Scoring was on a 5-point scale ranging from 'very satisfied' (score=1) to 'very dissatisfied' (score=5) with higher scores indicating less satisfaction with the service.

Receiving information and support to manage anticancer treatment related consequences:

Participants were asked to select where they sought support and information from a list of healthcare practitioners and other informal sources, such as family. Participants were also

asked to select predefined reasons for not seeking support or information when they had anticancer treatment related problems.

Overall wellbeing:

Overall wellbeing was assessed using a single-item assessment of quality of life: ‘How would you rate your overall wellbeing over the last week?’ [161]. The item was scored on a 5-point scale ranging from ‘as good as it can be’ (score=1) to ‘as bad as it can be’ (score=5) with higher scores indicating lower overall wellbeing.

The three free text items included were:

- Is there anything that we can improve to better support you in managing the side effects of anticancer treatment?
- Is there anything particularly good about the support you have had to manage side effects of anticancer treatment?
- Any other comments?

These questions allowed participants to comment on service elements and make recommendations for improvements in relation to supporting older people to manage anticancer treatment related consequences.

Participant age, gender and cancer diagnosis were recorded from medical records. Finally, participants were asked about their living arrangements and if they had any health conditions other than cancer.

3.5.3 Survey procedures

Researchers at the six study sites administered the final online questionnaire in person during February and March 2019. Researchers included research practitioners, nurses,

assistants, associates or administrators approved by the site study lead to take consent and administer the online survey. All researchers received training and were named on the study delegation log to perform study tasks. Researchers approached patients that met the study inclusion criteria. Informed consent was taken before researchers proceeded to the questionnaire items. The researcher recorded participant responses verbatim on tablet devices. The number of years since completion of primary anticancer treatment and reasons for not completing the survey were recorded wherever possible.

3.5.4 Sample size

Assuming an equal distribution of survey responses along a five-point scale, ranging from never experiencing an anticancer treatment related problem to always experiencing a problem, a sample size of 300 participants would provide a 95% confidence interval of ± 4.9% based on 75% of participants never experiencing an anticancer treatment related problem (score = 0).

3.5.5 Data analysis

The results of the survey were summarised using descriptive statistics in IBM SPSS® Statistics v25. Statistical significance was set at 0.05 (2-tailed). To indicate precision of sample estimates, 95% confidence intervals (CI) were reported for the proportion of participants experiencing anticancer treatment related consequences. Missing data were excluded from the analyses. Mann-Whitney U analyses were used to investigate differences in overall wellbeing scores between participants experiencing anticancer treatment related problems overall and across the seven domains and participants who did not experience problems. Mann-Whitney U analyses were undertaken as the sample distributions were not normal. A content analysis was undertaken with free text responses to identify main themes regarding proposed service improvements and perceptions of good quality cancer care.

The distribution (median and interquartile range) and missing values were examined for each item to explore the psychometric properties for the questionnaire used in the study. Floor or ceiling effects were considered present if more than 15% of participants scored the lowest or highest possible score on the scales, respectively [162].

3.6 Results

3.6.1 Participant characteristics

Of the 390 patients approached, 343 (88%) completed the questionnaire. The main reason for non-participation was refusal. Median (IQR) age was 74 years (70, 80) and 66% were male. Table 7 provides further details on participant characteristics. The most frequent diagnosis was prostate cancer. Over two-thirds of participants had other long-term health conditions, e.g., hypertension, diabetes and arthritis. Of the participants reporting to have other long-term conditions, n=137 (59%) had one, n= 57 (24%) had two, n=28 (12%) had three, and the remaining 5% had four or more other long-term conditions. Less than a quarter of the participants lived alone. The majority of participants who experienced side effects had completed primary anticancer treatment in the previous year.

Table 7: Participant characteristics

Characteristic	Measure	Value
Cancer diagnosis		
Prostate	No. (%)	221 (64)
Breast		110 (32)
Colorectal		12 (4)
Participant age		
65-70 years	No. (%)	91 (27)
71-75 years		104 (30)
76-80 years		76 (22)
81-85 years		57 (17)
86-90 years		12 (3)
> 90 years		3 (1)
Treatment status for participants experiencing anti-cancer treatment-related side effects (N = 170)*		
Completed primary anticancer treatment	No. (%)	61 (36)
On maintenance anticancer treatment		106 (62)
Missing		3 (2)
Time since completing primary anticancer treatment for participants experiencing anti-cancer treatment-related side effects (in months)		
	Median (interquartile range)	10 (3, 29)
	Minimum, maximum	1, 204
0-12 months	No. (%)	58 (17%)
13-24 months		15 (4%)
25-60 months		13 (4%)
61-120 months		9 (3%)
>120 months		7 (2%)
Missing		241 (70%)
Living arrangements		
Lives with partner/spouse/family/friend	No. (%)	259 (75)
Lives alone		81 (24)
Missing		3 (1)
Other health conditions(s)		
Yes	No. (%)	236 (69)
No		98 (29)
Don't know		4 (1)
Missing		5 (1)

* The denominator was 170, as data was only sought from participants reporting experiencing a consequence of anticancer treatment and not all participants.

3.6.2 Item distribution and missing values for the questionnaire used in this study

The median item scores varied depending on the scale and its response range (Appendix C, Tables C2-5). The median scores across the seven domains examined for the negative consequences of anticancer treatment ranged from 0 'never' to 2 'sometimes.' Most participants reporting a negative impact reported 'sometimes' experiencing it. Responses ranged from about 35% sometimes experiencing a negative impact on emotional wellbeing to about 14% sometimes experiencing a negative impact on the ability to manage other long-term conditions. The median scores for staff support to manage anticancer treatment related

consequences ranged from 2 ‘agree’ to 3 ‘neither agree nor disagree’ across the seven domains examined. Most participants reporting perceived staff support to manage the negative consequences of anticancer treatment selected ‘neither agree nor disagree’ across all domains, except *physical health* and *ability to deal with problems related to cancer or anticancer treatment*. Most items were not normally distributed, and floor effects were observed for most items (Appendix C, Figures C1-4), except for *social life* and *relationships* domains for the item related to staff support to manage consequences of anticancer treatment (Appendix C, Figure C2).

The frequency of missing responses ranged from 0.6% to 5.3% for items related to the negative consequence of anticancer treatment and from 6.8% to 13.3% for items related to staff support to manage consequences of anticancer treatment. The frequency of missing responses for satisfaction with general support and care after completing anticancer treatment was 1.8% and for overall wellbeing was 2.6%.

3.6.3 Prevalence of anticancer treatment related consequences and support to manage any consequences

Anticancer treatment related consequences were reported by n=170 (50%, 95% confidence interval 45% to 55%) participants. Of the participants experiencing problems, 61 (36%) had completed anticancer treatment and 106 (62%) were on maintenance anticancer treatment. The five most frequently reported side effects were hot flushes (n=47, 28%), gastro-intestinal problems such as mucositis, constipation and diarrhoea (n=42, 25%), musculoskeletal problems such as joint pain and muscle aches (n=42, 25%), fatigue (n=42, 25%) and skin problems such as itchy or dry skin (n=20, 12%).

Table 8 illustrates the extent to which anticancer treatment related consequences had a negative impact on participants and the extent to which participants felt adequately supported by hospital healthcare practitioners to manage the consequences. Participants

reported experiencing anticancer treatment related detrimental effects across all domains, of which an adverse impact on physical health, emotional wellbeing and social life were the most notable. Perceived support to manage anticancer treatment related consequences was highest for the physical health domain and most lacking for the domains of social life, managing other long-term conditions and relationships.

Table 8: Negative impact of anticancer treatment-related consequences in older cancer survivors and support to manage the consequences

Domain	Anticancer treatment-related negative consequence		Felt supported to manage anticancer treatment-related consequence	
	n[a]	% [95% CI]	n[a]	% [95% CI]
Physical health	138	40 [35-45]	83	24 [20-29]
Emotional wellbeing	116	34 [29-39]	55	16 [12-20]
Social life	82	24 [20-29]	22	6 [4-9]
Adjusting to life after cancer treatment	62	18 [14-22]	29	9 [6-12]
Dealing with problems related to cancer/treatment	57	17 [13-21]	35	10 [7-14]
Relationships with family/friends	53	16 [12-20]	14	4 [2-7]
Managing other long-term conditions	41	12 [9-16]	16	5 [3-7]

[a] Missing responses not included

For participants experiencing anticancer treatment related consequences, Mann-Whitney U tests revealed no significant difference in median scores across all domains between those who had completed anticancer treatment up to two years previously and those who had completed anticancer treatment more than two years previously (Appendix C, Table C8).

3.6.4 Satisfaction with the service for general support and care

For participants experiencing anticancer treatment related consequences, n=153 participants [90%, 95% CI 85% to 94%] were satisfied or very satisfied with care during treatment and n=52 [31%, 95% CI 24% to 38%] after completing anticancer treatment.

3.6.5 Preferred sources of information and support to manage anticancer treatment related consequences

Most participants contacted the hospital healthcare team when they experienced anticancer treatment related consequences. Cancer nurses were the most frequently reported contact (n=196, 69%) followed by oncologists (n=186, 65%). Participants also contacted primary care practitioners, such as general practitioners (n=129, 45%) and general practice nurses (n=25, 9%).

Family were a source of support and information to manage anticancer treatment related consequences for n=127 (44%) and friends for n=70 (24%) participants. Fifty-six participants (20%) sought information from the internet. Other practitioners such as pharmacists, physiotherapists, and psychologists were contacted by n=50 (17%) participants.

Fifty-nine participants (21%) reported not contacting anyone or seeking information when experiencing anticancer treatment related consequences. The reasons for not seeking support or information were that they did not need any support or information (46%), did not want to bother healthcare staff (29%), did not know who to ask (6%), and did not know where to look for information (3%).

3.6.6 Overall wellbeing

On the five-point scale with 1 indicating ‘As good as it can be’ and 5 indicating ‘As bad as it can be’, a Mann-Whitney U test revealed that participants who experienced anticancer treatment related consequences were significantly more likely to report poorer overall

wellbeing with a median (IQR) of 2 (1, 3) compared with 1 (1, 2) for those who did not experience anticancer treatment-related consequences (U = 11263, p = 0.001). Table 9 compares the overall wellbeing scores for participants who reported anticancer treatment-related consequences across the seven domains and those who did not. For all domains except physical health, participants who experienced anticancer treatment related consequences were significantly more likely to have a lower overall wellbeing score.

Table 9: Overall wellbeing scores for anticancer treatment related consequences (N=169)

Domain	Experienced anticancer treatment-related consequence		Did not experience anticancer treatment-related consequence		p
	n	Median (IQR)	n	Median (IQR)	
Physical health	138	2 (1, 3)	31	2 (1, 2)	0.147
Emotional wellbeing	117	2 (1, 3)	52	1 (1, 2)	<0.001
Social life	85	2 (1, 3)	84	1 (1, 2)	<0.001
Relationships with family/friends	55	3 (1, 3)	114	2 (1, 2)	<0.001
Ability to deal with problems related to cancer/treatment	61	2 (2, 3)	108	1 (1, 2)	<0.001
Ability to manage other long-term conditions	44	2 (2, 3)	125	2 (1, 3)	0.016
Ability to adjust to life after cancer treatment	70	2 (1, 3)	99	2 (1, 2)	<0.001

For participants who experienced consequences of anticancer treatment, the median (IQR) overall wellbeing score was 1 (1, 2) for those who completed anticancer treatment in the previous two years, compared with a score of 2 (2, 3) for those who completed anticancer treatment more than two years previously; this was not statistically significant (p = 0.06).

3.6.7 Experience of care and recommendations to improve support to manage anticancer treatment-related consequences

Comments on good aspects of care and support were provided by n=297 (87%) of participants and n=285 (83%) provided suggestions to better manage consequences of

anticancer treatment. Figure 11 provides illustrative quotes of areas of good practice and suggestions for service improvements. Three themes emerged from the free text responses: access to healthcare practitioners, services and information, which are reported below.

Access to healthcare practitioners

Regular visits or communication regarding management of anticancer treatment related consequences seemed to allow participants to build rapport with dedicated healthcare practitioners. Where participants did not have access to dedicated healthcare practitioners, they found it difficult to know whom to contact when they experienced anticancer treatment related side effects. This raised their anxiety at a time when they already felt anxious.

Access to support services

Participants who reported receiving care from integrated hospital and community care teams felt they had ready access to support when it was needed. Participants suggested that hospital services could be designed to minimise waiting times both for routine and emergency appointments, providing an out-of-hours and weekend service and improved integration with local community services to ensure continuous access to support services.

Access to information

Participants commented that they would have liked more information about potential side effects before the start of anticancer treatment, which would have prepared them to identify and manage them. Healthcare teams that provided participants with a wide range of information at the start of treatment helped to manage their expectations. Participants further suggested that more support could be offered to families as witnessing anticancer treatment related side effects in loved ones could be emotional.

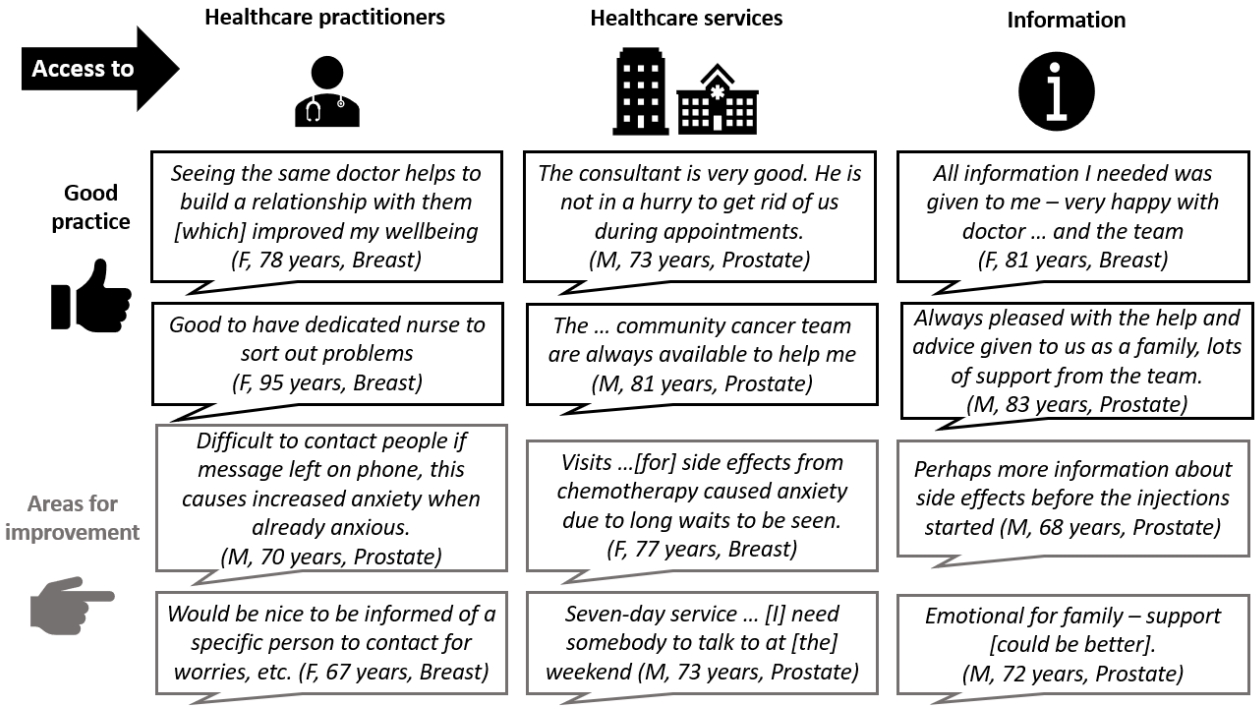

Figure 11: Themes and illustrative quotes for open-ended questions on good practice and areas for improvement to support older people manage anticancer treatment related consequences

3.7 Discussion

This cross-sectional study estimated the negative impact of long-term anticancer treatment in older cancer survivors. It also explored the extent to which current cancer services support older cancer survivors to manage anticancer treatment related consequences. As anticipated, anticancer treatment related physical and emotional consequences were most widely reported. Most participants felt supported to manage these physical and emotional side effects. Of concern was that anticancer treatment related consequences also negatively impacted on social life and ability to adjust to life after cancer treatment, for which perceived support from healthcare practitioners was inadequate.

Unmet social and relationship problems and the ability to manage other long-term conditions were the most frequently identified unmet needs in older cancer survivors in this study which differs from previous studies, which report unmet physical and psychological needs [61, 139]. Participants were included if they had completed initial anticancer treatment such as

monotherapy or in combination with other types of cancer treatment, such as, surgery or radiotherapy. This may have led to over-reporting of side effects if participants could not distinguish between the impact of anticancer treatment from those of surgery or radiotherapy. The majority of older people reported living with co-morbidities which further increases the complexity of survivorship care [163]. This interplay between cancer and comorbidities in older people highlight the need for healthcare practitioners to avoid viewing consequences of cancer treatment in isolation.

Reduced social activity due to poor physical health or emotional problems before starting anticancer treatment could increase the risk of anticancer treatment related toxicity [164]. This study found that support for managing social consequences and adjusting to life after initial anticancer treatment was lacking. It is possible that healthcare teams either could not recognise or did not know how to address these unmet needs. A significant proportion of patients reported not wanting to further burden the healthcare team with their experiences of anticancer treatment related negative consequences. There is therefore a need to explore approaches to support both healthcare teams and patients to identify and address anticancer treatment related psychosocial consequences. There have been calls for supporting survivors to self-manage to be active partners in cancer care by empowering and enabling them to recognise, report and manage their disease, health and wellbeing [75]. This will require a change in mindset where cancer survivors and healthcare practitioners see themselves as equal partners in care and where new service models are developed to integrate self-management support into routine survivorship care.

This study also revealed that older people may not receive the help they need to adjust to life after completing anticancer treatment. One strategy suggested to improve care during this transition is identifying older people who may be at risk of developing long-term side effects before they have completed anticancer treatment [165]. This could be achieved using tools validated for providing cancer-specific geriatric assessments [166, 167]. Survivorship

or patient navigators may help to improve care co-ordination between specialists and primary care providers and facilitate patient-provider communication by eliminating barriers to timely and person-centred survivorship care across different healthcare settings [168, 169].

Although the majority of participants in this study had completed anticancer treatment up to two years previously, data from the small number who reported completing anticancer treatment beyond this period were also included in the analyses. Researchers from each site were responsible for selecting eligible patients. They may have misinterpreted the eligibility criteria or it may have been challenging for the site research teams to find the date of completion of initial anticancer treatment. This is particularly relevant if the patient received treatment elsewhere or received multiple types of anticancer treatments. Further, researcher error in reporting the date of completion of anticancer treatment cannot be ruled out. Despite not having the anticancer treatment completion date for a small number of participants, overall wellbeing scores were compared. The overall wellbeing scores were relatively high in this study. This is possibly related to older people having better coping skills as a result of more life experience. Further, the impact of cancer and its treatment may be low in older people due to likely fewer financial pressures, lower social demands and more opportunities for peer support.

The median overall wellbeing scores for participants who had completed anticancer treatment more than two years previously were worse than for those who had completed anticancer treatment up to two years previously. Despite the lack of statistical significance, this finding may be at odds with the current evidence suggesting that most cancer treatment related symptoms will resolve after the first year in most cancer survivors [155]. There could be several explanations for this. The median age of participants who had completed anticancer treatment over two years previously was higher (78 years) than for those who had completed anticancer treatment up to two years previously (72 years). Increasing age is

associated with decline in the body's drug handling ability, more comorbidity and poorer tolerance to anticancer treatments [9, 11]. Additionally, the finding could be explained by the presentation of late effects of anticancer treatment. All participants attended follow-up cancer clinics, where patients are generally followed up for 3-5 years. However, this can vary depending on cancer type and local cancer pathways. It is possible that patients were not 'discharged' from the cancer care team because of complex care needs leading to our findings of poorer overall wellbeing scores. This suggests that interventions to address the needs of older cancer survivors will need to consider the most appropriate setting for offering ongoing support, beyond treatment completion.

Differentiating between anticancer treatment related side effects and consequences from the cancer itself or simply older age can be challenging. For example, in this study 25% of participants reported experiencing fatigue, which is similar to that reported in the general population, where about 26% of males and 23% of females aged 60-69 years experienced fatigue [170]. Similarly, in this study 25% of participants experienced musculoskeletal problems, such as, pain. In the general population in people aged 60-69 years, pain was experienced in about 25% of males and 22% of females [170].

In this study, participants mostly sought information and support from secondary care practitioners, such as cancer nurses and oncologists, suggesting that primary care teams might be an untapped resource for addressing unmet needs of older cancer survivors, which are shown in the present study. This may be particularly relevant for older people living with cancer and multiple long-term conditions. Mainly seeking information and support from the secondary care team is reflective of historical follow-up cancer care models in the UK, involving routine face-to-face hospital appointments with cancer specialists post anticancer treatment completion [171, 172]. As the population of cancer survivors grows, increased consultations are likely to have a significant impact on the workload and capacity in secondary care. Secondary care is also focused on more specialist support compared to

primary care, whereas older cancer survivors may need a more holistic approach to support. Alternative models to delivering support to older people with long-term anticancer treatment related consequences are warranted. Future survivorship care models to support older people to manage anticancer treatment related long-term consequences should consider, firstly, who might be best placed to address issues related to anticancer treatment. Secondly, whether interventions other than those delivered face-to-face, e.g., telephone or online/video conferencing are appropriate for older people. COVID-19 has accelerated the use of technology, offering innovations in the delivery of survivorship care [173-176]. However, while technology-based interventions may be promising in the delivery of cancer survivorship care, careful consideration will be needed to avoid widening healthcare disparities in those with low technology literacy or access [177]. The present study found that only one in five older cancer survivors sought information from online sources. And finally, the role of self-management interventions to empower older survivors to play a more active role in their health and wellbeing needs exploration. The present study showed that some older cancer survivors did not know who and how to access support from healthcare practitioners. Self-management with the support from practitioners may offer a solution. However, careful consideration will be needed of the preference, acceptability and confidence of the older person to self-manage.

Limitations of the study stem mainly from the cross-sectional study design that precludes monitoring of trends over time or inference of causation. The questionnaire used in this study was not a validated measure and may therefore be subject to measurement error and conclusions drawn may need to be interpreted cautiously. The overall wellbeing measurement in the questionnaire referred to the very recent past (the last week), whereas most other wellbeing measures refer to a broader time period, such as, the last four weeks. Some questionnaire items were limited to participants experiencing anticancer treatment related side effects, such as, primary treatment completion status and time since completing primary treatment. The online survey was designed to be administered by researchers.

However, in some cases researchers allowed participants to answer a paper questionnaire when they had technical problems or poor internet connectivity, which could have led to misinterpretation of questions. For example, a proportion of participants may have misinterpreted ‘anticancer treatment’ as referring to any type of treatment, e.g., surgery or radiotherapy and not anticancer (drug) treatment exclusively. Despite the survey being short, some data were missing. The data were derived from older people with breast, colorectal or prostate cancers from two regions in England; generalisability might therefore be limited by this geography and the range of solid cancers. Additionally, most participants had a prostate cancer or breast cancer diagnosis and would have likely been on hormonal treatment, which can have significant side effects. The findings may therefore be limited to older people on hormonal treatment for these cancer types. The name and number of cycles of initial anticancer treatment received were not recorded, nor were any subsequent anticancer treatments, which could influence the types of side effects experienced by participants. There was wide variation in the time since initial anticancer treatment, from one month to over 10 years, which likely resulted in poor recall of experiences. Future surveys will need to incorporate details of treatment received and limit time periods.

3.8 Chapter summary

This cross-sectional study has identified the size and scope of the unmet physical and psychosocial needs of older cancer survivors after completing anticancer treatment.

The contribution of this chapter to the development of the logic model is the identification of the problem to be addressed and is shown in figure 12.

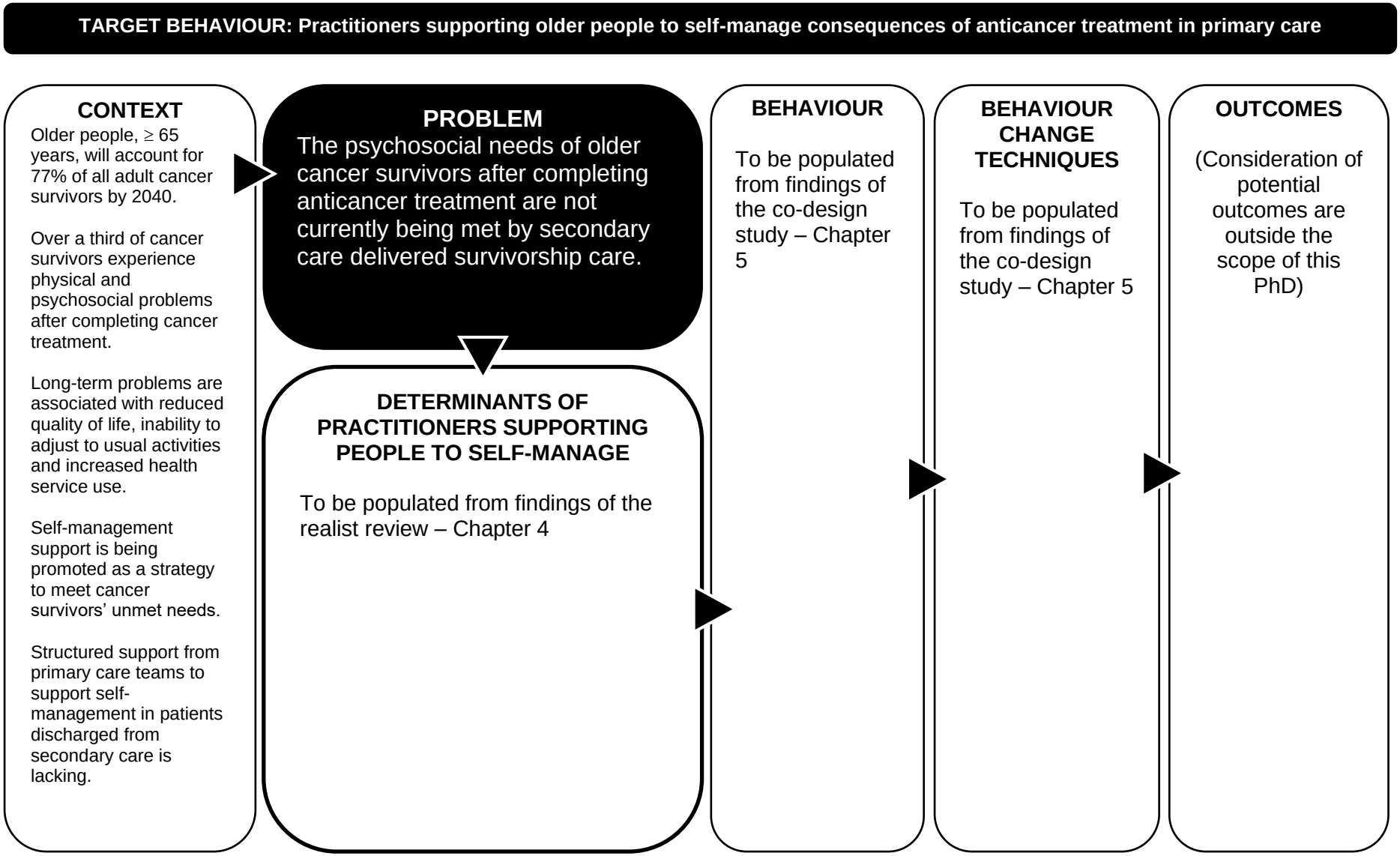

Figure 12: Logic model: contribution of the cross-sectional study to identify the problem to be addressed

This study identified perceived gaps in service provision for older cancer survivors with regards to access to social support and adjusting to life after completing anticancer treatment. Provision of patient-centred support to meet the complex needs of the growing number of older people living with anticancer treatment-related consequences will require consideration of:

- the ideal setting for providing ongoing support, e.g., primary, secondary or community care,
- who might be best placed to provide the support, e.g., nurses versus other healthcare practitioners,
- patient preference and acceptability of the proposed intervention, e.g., face-to-face or digital support

In addition, the following recommendations arising from this study could inform future intervention development:

- Awareness of how to identify and address anticancer treatment related problems needs to be raised among both healthcare practitioners and older cancer survivors.
- Cancer survivors need to be empowered to facilitate a partnership approach to their care and wellbeing. This could be achieved through embedding support for self-management in routine care, in those cancer survivors that are able and willing to do so.
- Care co-ordination between hospital and primary care teams needs to be strengthened.
- Ongoing support and follow-up could facilitate early identification and management of late effects of anticancer treatment.

This chapter has highlighted the key domains to consider during the design of an intervention to address the long-term support care needs of older cancer survivors. The

potential role of healthcare practitioners in supporting cancer survivors to self-manage has been highlighted in Chapter 1. However, before a self-management support intervention for cancer survivors can be developed it is important to understand what works well or not for healthcare practitioners. The next chapter, Chapter 4, will describe the barriers and enablers to practitioners delivering self-management support to adult cancer survivors, using a realist approach and underpinned by the Theoretical Domains Framework, both described in Chapter 2.

Chapter 4 Facilitating healthcare practitioners to deliver self-management support in adult cancer survivors: a realist review

4.1 Introduction

Part of this chapter is derived from the publication:
Kantilal K, Hardeman W, Whiteside H, Karapangiotou E, Small M, Bhattacharya D. Realist review protocol for understanding the real-world barriers and enablers to practitioners implementing self-management support to people living with and beyond cancer. *BMJ Open* 2020;10:e037636. doi:10.1136/bmjopen-2020-037636

Chapter 1 provided an overview of the growing numbers of cancer survivors living with treatment related problems. The role of self-management was introduced as a strategy promoted by many health systems to empower people to play an active role in managing their own health and reduce the future demands on health services. Key tasks in cancer self-management were described, such as, monitoring symptoms, taking medication and communicating with healthcare practitioners [39, 72]. Self-management support refers to the strategies used by healthcare practitioners to increase patient capacity to self-manage. The two types for self-management support were presented, one that targets patients and another that targets healthcare practitioners [73, 74]. An argument was made for developing interventions that target healthcare practitioners to promote care equity.

As mentioned in Chapter 2, systematic reviews on self-management support in cancer survivors have been undertaken, however, they have failed to identify the key components for their successful implementation, mainly due to the complex and heterogenous nature of interventions and the lack of theory-driven approaches [77, 79, 81, 116]. Realist approaches have been argued to be better suited than traditional systematic reviews to make sense of

complex and heterogenous interventions by identifying the causal mechanisms involved in their success or failure and by considering the setting and context in which they are delivered [96, 117].

The limited evidence available for healthcare practitioner targeted interventions described very broad components that facilitated healthcare practitioners to support cancer survivors to self-manage. This included a cultural shift, understanding of what self-management support involves and adequate resources to deliver self-management support [86]. Chapter 1 mentioned the need for a systematic theory-based approach, such as, a realist review to characterise self-management support interventions [87]. This will enable understanding of the nature of the behaviour to be changed and identify any additional intervention components and mechanisms influencing successful implementation and sustainability of interventions within particular contexts or settings [85, 87]. A realist review was therefore done to identify the barriers to and enablers for facilitating practitioners to support self-management among adult cancer survivors and is detailed in this chapter.

Chapter 2 emphasised the need to use theory when developing complex interventions such as self-management support [90]. A realist approach, underpinned by the Theoretical Domains Framework (TDF) was selected to explore the barriers and enablers for facilitating healthcare practitioners to deliver self-management support to cancer survivors. A major advantage of the TDF is that its domains have been mapped to behaviour change techniques which are the active ingredients of interventions. This mapping facilitates selection of the most effective components when designing theory-based interventions to change practitioner behaviour [120], which is explored further in chapter 5.

4.2 Aim

This realist review aimed to improve understanding of the barriers to and enablers for facilitating healthcare practitioners to provide self-management support to cancer survivors.

4.3 Overarching research question

The overarching question guiding this realist review was: What works for whom and in what circumstances in relation to facilitating healthcare practitioners to provide effective self-management support in people living with long-term consequences of anticancer treatment?

4.4 Ethics approval

The study was reviewed by the University of East Anglia Faculty of Medicine and Health Sciences Research Ethics Committee (reference 201819 – 124). The study approval letter is provided in Appendix D.

4.5 Methods

Pawson *et al* have proposed a method for conducting realist reviews [96]. However, there is freedom to interpret the method and customise the steps [111, 113, 178]. This study was guided by five iterative steps to: (1) Define the review scope, (2) Develop initial programme theories, (3) Search for evidence, (4) Select and appraise evidence, and (5) Extract and synthesise data [96]. Figure 13 provides an overview of the review design. The Realist and Meta-narrative Evidence Syntheses: Evolving Standards (RAMESES) publication standards guided the reporting of this study [179], and is included in Appendix E.

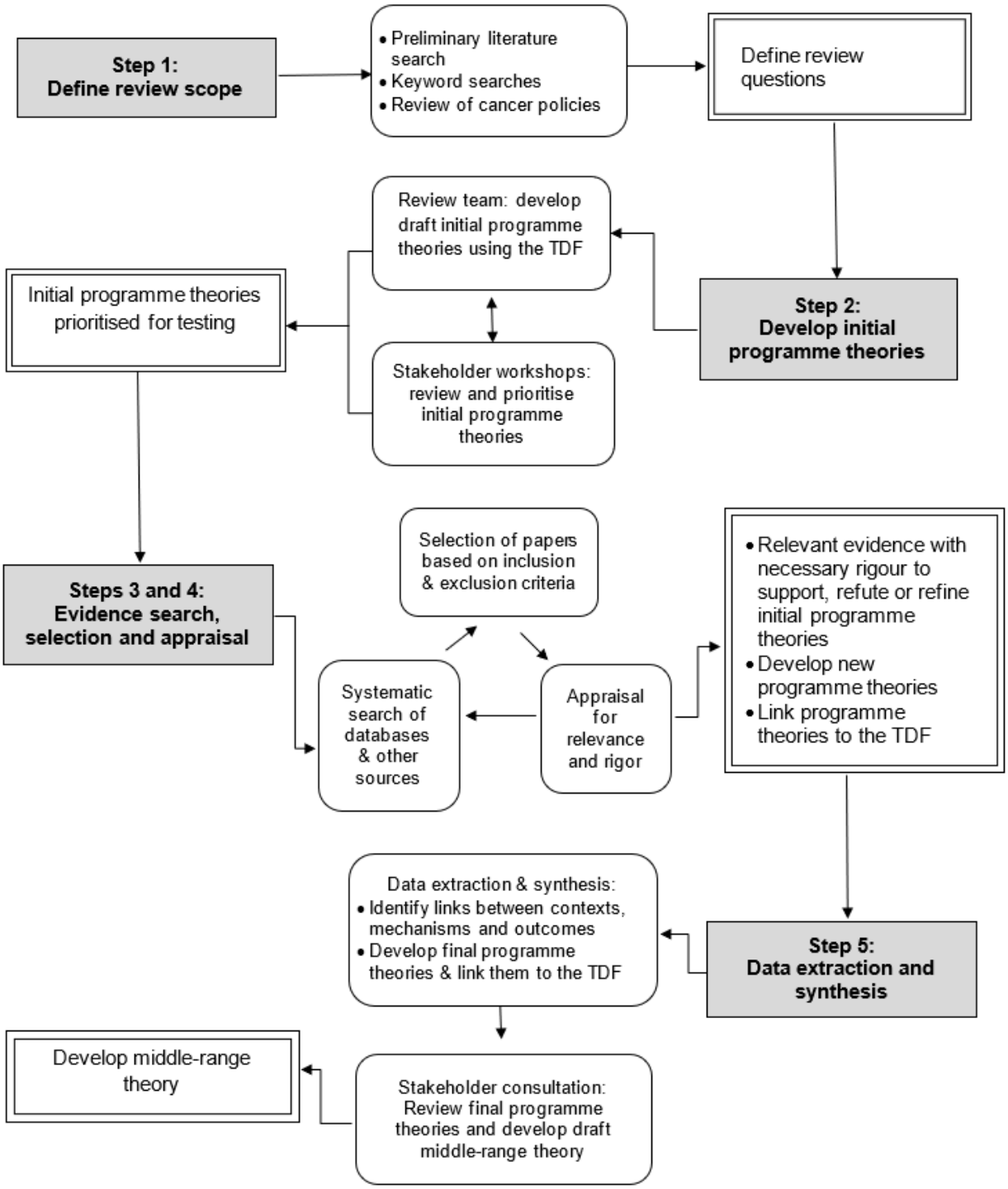

Figure 13: Overview of realist review design
(TDF=Theoretical Domains Framework)

4.5.1 Step 1 – Define the review scope

Before undertaking formal searches, the realist review scope was established. A preliminary literature search was undertaken to identify the existing literature about barriers and enablers for healthcare practitioners promoting self-management among adult cancer survivors. The search also explored how self-management support interventions sought to address the needs of cancer survivors. The preliminary search involved several steps. To identify relevant systematic reviews, PubMed and The Cochrane Library were searched, using the following search terms: cancer survivors, healthcare professionals and self-management or self-care. Additionally, keyword searches in Google Scholar and the National Institute for Health and Care Excellence (NICE) Evidence search were undertaken to identify literature reviews and primary studies on self-management support in the cancer setting. Finally, national and international cancer policy documents were reviewed [8, 20, 28, 180].

The preliminary search generated the following questions for the realist review:

i. What are the barriers and enablers to facilitating healthcare practitioners to provide self-management support to adult cancer survivors?
ii. What are the healthcare practitioner skills and behaviours needed to implement self-management support interventions among adult cancer survivors?
iii. What are the intended and unintended outcomes for patients, organisations and the wider health system of interventions which target healthcare practitioner delivery of self-management support?
iv. What are the mechanisms by which interventions to facilitate healthcare practitioners to deliver self-management support result in their outcomes?
v. What are the contexts that influence mechanisms involved in interventions to facilitate healthcare practitioners to deliver self-management support?

4.5.2 Step 2 – Develop initial programme theories

The TDF was applied to the ideas generated from the preliminary search (step 1) and experiences of the review team (KK, DB, WH and HW) to develop initial programme theories (PTs). PTs are potential explanations for how intervention content or components achieve their desired outcomes. Realist PTs illustrate the relationship between contexts, mechanisms and outcomes and are often expressed as context-mechanism-outcome configurations (CMOCs).

The initial PTs were written in the form of 22 explanatory statements. The statements contained references to context, mechanism and outcomes, although not all statements contained all elements at this stage.

Stakeholders helped to review and prioritise ten initial PTs to test against the literature. Three stakeholder workshops were organised. Stakeholders were recruited from the following cancer support and research groups known to the review team: Big C, Norfolk's cancer charity, Macmillan Cancer Support, South East London Consumer Research Panel for Cancer and the Norfolk Local Pharmaceutical Committee. The first two workshops involved mixed groups of adult cancer survivors, caregivers, healthcare practitioners such as nurses and allied health professionals, commissioners and cancer charity representatives, and the third workshop involved community pharmacists.

Stakeholders prioritised the initial PTs using a two-step process. Firstly, participants were invited to complete an online survey before the workshop to rate each initial PT as 'important', 'not important' or 'unsure.' A copy of this online survey can be found in Appendix F. Secondly, after the results of the online survey were presented at the start of each workshop, participants discussed the PTs to allow selection and agreement of ten initial PTs to take forward for further testing. Selection of the PTs for discussion at the workshops and

prioritisation were based on an *a priori* criterion of 70% stakeholder agreement [181]. Initial PTs were prioritised as follows:

- if 100% of survey participants agreed that the PT was important it was selected for testing,
- if 70-99% of survey participants agreed that the PT was important it was discussed at a workshop, and
- if less than 70% of participants agreed that the PT was important it was not selected for further discussion and hence discarded.

4.5.3 Step 3 – Evidence searches

This step involved identifying suitable papers to test and refine the ten initial PTs selected in step 2. The following electronic databases were searched, from inception to September 2019: Medline, EMBASE, CINAHL, Scopus, PsycINFO, ERIC and AMED. Search terms were developed in discussion with the review team. An example search in Medline is provided in Appendix G. The inclusion and exclusion criteria developed to focus the review are provided in table 10.

Table 10: Realist review inclusion and exclusion criteria

Inclusion criteria	
P – Population	Practitioners, e.g., doctors, nurses, pharmacists, allied health professionals, supporting self-management in adult cancer survivors. Patient, caregiver or manager perspectives on practitioner implementation of support of self-management consultations in adult cancer survivors.
I – intervention	Methods that promote the uptake of self-management support interventions or the provision of self-management support programmes, targeted to adults (>18 years) living with cancer in the post treatment/survivor stage of the cancer pathway.
C – Comparator	None
O – Outcomes	Outcomes of interest will depend on the nature of the intervention, but could include: Practitioners, e.g., knowledge/skills/behaviours needed to support self-management and signposting patients. Patients, e.g., adjustments/acceptance of self-management, shared decision making, relationships with practitioners. Process or implementation outcomes, e.g., health service use, change in care delivery.

H – Healthcare context	Any healthcare setting that provides care to adult cancer populations, e.g., hospital, ambulatory care, outpatient care, community services/organisations, primary care practice, digital (e.g., telehealth, app- or web-based).
Study design	
• No restriction on study design. • Include non-empirical sources (i.e., grey literature), e.g., opinion papers, books, guidelines, policies, editorials, dissertations, etc. through citation searches and identification by the review team and stakeholders.	
Exclusion criteria	
• Self-management support interventions in the following phases of the cancer pathway: early detection, prevention, active treatment and end-of-life care. • Self-management support interventions for managing consequences of radiotherapy or surgery only. • Papers describing patient education, patient experiences or patient behaviour change that do not report health professional guided strategies to support behaviour change to manage problems or adjust to life after cancer treatment. • Non-English papers	

The traditional data source for realist reviews is secondary data from published documents. In this study, unpublished experiences of developing or delivering self-management support interventions were combined with published data. An online practitioner survey was developed to capture real-world data of unpublished interventions which targeted practitioner delivery of self-management support in any healthcare setting, shown in Appendix H. This approach allowed exploration of relevant interventions that had not been published and provided insights into the mechanisms that operated in particular contexts to produce outcomes. The strategies used for conducting realist qualitative interviews were adopted to develop realist theory-driven survey questions [182]. Survey questions were open-ended, producing qualitative data. A purposive sampling approach was used to identify potential survey participants. These included members of UK cancer societies, whose membership included practitioners from primary, community and secondary care settings, such as the British Oncology Pharmacy Association and UK Oncology Nursing Society. Research and advocacy groups known to KK and the supervisory team involved with developing or

evaluating self-management support services for cancer survivors were also invited to complete the online practitioner survey.

Ethical approval from the University of East Anglia Faculty of Medicine and Health Sciences Research Ethics Committee was received and the survey was piloted before distribution. Once the British Oncology Pharmacy Association and UK Oncology Nursing Society agreed to circulate the survey to their members, a link to the survey together with an invitation email was sent inviting potential participants to share their experiences. The survey was open for two months initially, from November to December 2019, but was extended to March 2020 as few responses were received. Responses were eligible if they described the development or delivery of self-management support interventions targeted at healthcare practitioners to facilitate delivery of self-management support to adult cancer survivors who had completed initial cancer treatment. Data were collected on service design and delivery such as a description of the service, details about who developed and delivered the service, the patient groups targeted, and details about what worked or not, and why. Respondents were asked to provide their contact details if they agreed to be contacted to provide further information or answer queries related about their intervention. Completion of the survey was voluntary. Only the review team had access to the personal details of participants, which were kept secure. Participants were able to withdraw at any point, without giving a reason. All data were handled in accordance with the University of East Anglia's data protection requirements for webforms (Data Protection For Webforms - About - UEA).

4.5.4 Step 4 – Selection and appraisal of evidence

A systematic method was used for study screening and selection, using Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidance [183]. Two reviewers (KK and HW) independently screened papers first by title and abstract and then full text. Papers in a non-English language were excluded at title and abstract screening stages.

Disagreements were resolved by discussion with a third reviewer (DB) to ensure that there was consistency in paper inclusion.

Inclusion criteria in realist reviews depend on the rigour and relevance of reported evidence to inform the development of CMOCs [96]. Documents were selected based on their relevance to contributing to PT development or testing. Criteria were developed to help with the initial study selection process in relation to relevance. Table 11 summarises the relevance ranking criteria to distinguish between conceptually rich and weaker evidence for providing explanations for PT development. Documents were further reviewed with respect to rigour in terms of credibility and trustworthiness. Studies were included if deemed "good enough" in terms of robustness of the study and its conduct, by considering issues such as sample size, data collection, data analysis and claims made by study authors [111]. The traditional evidence hierarchy is not applicable to realist reviews [107, 184]. Realists argue that useful causal information can arise from seemingly poor quality studies and can provide rich insights for PT development [184]. Evidence of lower quality was hence considered if relevant for developing PTs in this study.

Table 11: Criteria to rank relevance of study to programme theory development

High relevance	• Relates to adult cancer survivors and describes the implementation of a self-management support activity initiated by practitioners or targeting practitioner behaviour change • Relates to supporting adult cancer survivors and describes training of practitioners in providing self-management support • Relates to supporting adult cancer survivors and includes description of practitioner views and experiences of self-management support • Describes studies on the perspectives of patients, caregivers or managers on practitioner implementation of support of self-management in consultations with adult cancer survivors
Moderate relevance	• Relates to adult cancer survivors and includes description of patient experience of interacting with practitioners supporting self-management • Describes experiences of adult cancer survivors who have been provided with self-management support

	• Describes implementation of practitioner initiated self-management support in chronic diseases (including cancer)
Low relevance	• Self-management support in adult cancer survivors are described but involvement of practitioners in its delivery is unclear • Describes implementation of practitioner-led self-management support activity during other stages of the cancer journey (i.e., not the survivorship stage) • Quantitative data on self-management support intervention • Describes self-management support needs of adult cancer survivors
No relevance	• Does not meet any of the above criteria

4.5.5 Step 5 – Data extraction and synthesis

A bespoke Excel data extraction form was developed and piloted for this study. Data were independently extracted by two reviewers (KK and HW) and included the following: study aims, design and methods, study participants (e.g., type of healthcare practitioners and cancer survivors), study outcomes, and information relevant to PTs and emerging CMOCs. Additionally, author explanations and discussions about how an intervention was assumed to work or not were considered. Individual papers had segments that contributed to different parts of a PT and therefore needed several readings to extract applicable data.

Sections of relevant text from papers and the online survey were coded and imported into the Excel data extraction form. Some codes originated from the papers and the online survey (inductive codes) and others from the initial PTs (deductive codes). Coded texts were based on whether the evidence referred to context (C), mechanism (M) and/or outcome (O).

Data were extracted and coded from qualitative, quantitative and mixed methods studies separately. The extracted coded text from different study designs were then synthesised together according to the relationship between contexts, mechanisms and outcomes. Emerging patterns of contexts and outcomes and the possible mechanisms were identified

[111, 117]. Data synthesis involved reflection and discussion among the review team. The integrity of each PT was examined to determine if it was supported by empirical evidence. Additionally, competing PTs were considered and how the PT was influenced by different settings. How the emerging PTs compared to practical experiences of healthcare practitioners and patients was also considered [117].

Data from the papers and online survey were used to confirm, refute or refine the PTs and to identify new PTs. During refinement, to ensure consistency and illustrate emerging links between contexts, mechanism and outcomes, all PTs were expressed as 'if-then' statements [185]. The refined and new PTs were linked to the TDF to help explain the emerging patterns and identify barriers and enablers for practitioner behaviour change. The survey data allowed comparison of PTs to real-world experiences of healthcare practitioners. The final PTs were presented as Context-Mechanism-Outcome configurations (CMOCs) grounded in evidence from the published literature and practitioner surveys. The links between contexts, mechanisms and outcomes were shown using 'if … then … because' statements.

4.6 Results

4.6.1 Initial development and prioritisation of programme theories for testing

Informed by the preliminary literature search, 22 initial PTs were developed, displayed in table 12, with multiple PTs spanning all 14 domains of the TDF.

The three stakeholder workshops had 39 participants, comprising 21 adult cancer survivors, one caregiver, 14 healthcare professionals, two cancer charity representatives and one commissioner. Figure 14 provides the flow of PTs across the three stakeholder prioritisation workshops. The process led to a final ten PTs for testing and refinement against the published literature and the practitioner survey.

Table 12: Initial programme theories derived using the Theoretical Domains Framework (TDF) and the ten programme theories prioritised for testing in the realist review

TDF Domain (Definition)	**No.**	**Programme Theory**	**Prioritised for testing**
1. Knowledge What knowledge does the practitioner need (An awareness of the existence of something)	1	Practitioners will be effective in supporting patients to self-manage if the practitioner has the required knowledge about the cancer pathway	Yes
	2	Practitioners will correctly identify and signpost patients to self-manage if the practitioner has the required knowledge about the consequences of anti-cancer treatment.	Yes
2. Skills What are the required skills of the patient/practitioner? (An ability or proficiency acquired through practice)	3	Practitioners are more likely to initiate discussions regarding self-management with patients and carers if they feel equipped to conduct consultations with patients and carers experiencing emotional distress.	No
3. Social/ professional role and identity Does the activity fit with what the patient/practitioner thinks that they should be doing? (A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting)	4	Practitioners are more likely to initiate discussions regarding self-management with patients and carers if they feel that it is a part of their role.	No
	5	Practitioners are more likely to initiate discussions regarding self-management with patients and carers if they feel that this role is endorsed by colleagues from other professions.	No
	6	Self-management support is more likely to be successful if the primary care team are united in their vision of how it should be achieved.	Yes
4. Beliefs about capabilities Does the patient/practitioner feel that they have the capability and control over the situation to do the required behaviour? (Acceptance of the truth, reality or validity about an ability, talent or facility that a person can put to constructive use)	7	If a practitioner is confident that they have the required knowledge and skills, then they are more likely to engage patients and carers in discussions about self-management support.	Yes
5. Optimism Confidence that the desired behaviour/goals will be achieved, and that the outcome will be good (The confidence that things will happen for the best or that desired goals will be attained)	8	If a practitioner feels that signposting patients to self-manage can be integrated into their current role, they are more likely to try doing it.	Yes
6. Beliefs about consequences What good/bad things does the person think will happen if they do the required behaviour? (Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation)	9	If a practitioner believes that the self-management package is safe, then they will be more likely to encourage patients to engage with it.	Yes
	10	If a practitioner believes that supporting self-management will improve relationships with their patients, then they will be more likely to encourage patients to engage with it.	No
	11	If practitioners believe that initiating discussions about self-management	No

		will be time consuming, then they will be less likely to engage patients in discussion.	
7. Reinforcement Is there a dependent relationship between undertaking/not undertaking the required behaviour and some outcome that will impact on the individual? E.g., reward or sanction**.** (Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus)	12	If organisations provide rewards or sanctions dependent upon whether practitioners perform/do not perform self-management support, then practitioners are more likely to undertake signposting to self-management support.	No
8. Intention Conscious decision to perform the required activity (A conscious decision to perform a behaviour or a resolve to act in a certain way)	13	If organisations work with practitioners to integrate self-management into routine practice, then practitioners are more likely to engage with it.	Yes
9. Goals Does the required behaviour align with the goals of the individual undertaking the behaviour? (Mental representations of outcomes or end states that an individual wants to achieve)	14	If the organisation demonstrates an expectation that supporting patients to self-manage is a part of the practitioner's role, then they are more likely to engage.	No
	15	If systems are organised to encourage and prioritise self-management support then this will more likely lead to practitioners feeling supported and equipped) to engage in self-management support, resulting in self-management support becoming part of the culture of care.	Yes
10. Memory, attention and decision making Ability to retain the required information and apply to make decisions. (The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives)	16	If organisations work with practitioners to integrate a prompt for self-management support into routine practice, then practitioners are more likely to remember to broach the topic of self-management support.	No
11. Environmental context and resources Any circumstance of the situation or environment that facilitates or hinders the required behaviour. (Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence and adaptive behaviour)	17	Additional funding is required to enable capacity to be built into the team for practitioners to deliver this new role of supporting self-management support.	Yes
12. Social influences Social pressure/norms/ group conformity (Those interpersonal processes that can cause individuals to change their thoughts, feelings, or	18	Practitioners are more likely to initiate discussions regarding self-management with patients and carers if there are role models demonstrating that it can be done.	No
	19	If systems are organised to encourage self-management support, then	No

behaviours)		self-management support is more likely to become part of the culture of care.	
	20	If organisations and practitioners feel that the concept of self-management support is supported by patients and carers, then they are more likely to engage with implementing a self-management support programme.	No
13. Emotion Positive or negative emotions created by undertaking the required behaviour. (A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event)	21	Decision tools such as a traffic light system for when patients should seek hospital advice will reduce anxiety for practitioners arising from the fear that an emergency situation may be missed.	Yes
14. Behavioural regulation Anything that can be monitored to see how the person is doing and give them feedback (Anything aimed at managing or changing objectively observed or measured actions)	22	If organisations routinely monitor and feedback on practitioner engagement with self-management support, then they are more likely to initiate and maintain support of a self-management support programme.	No

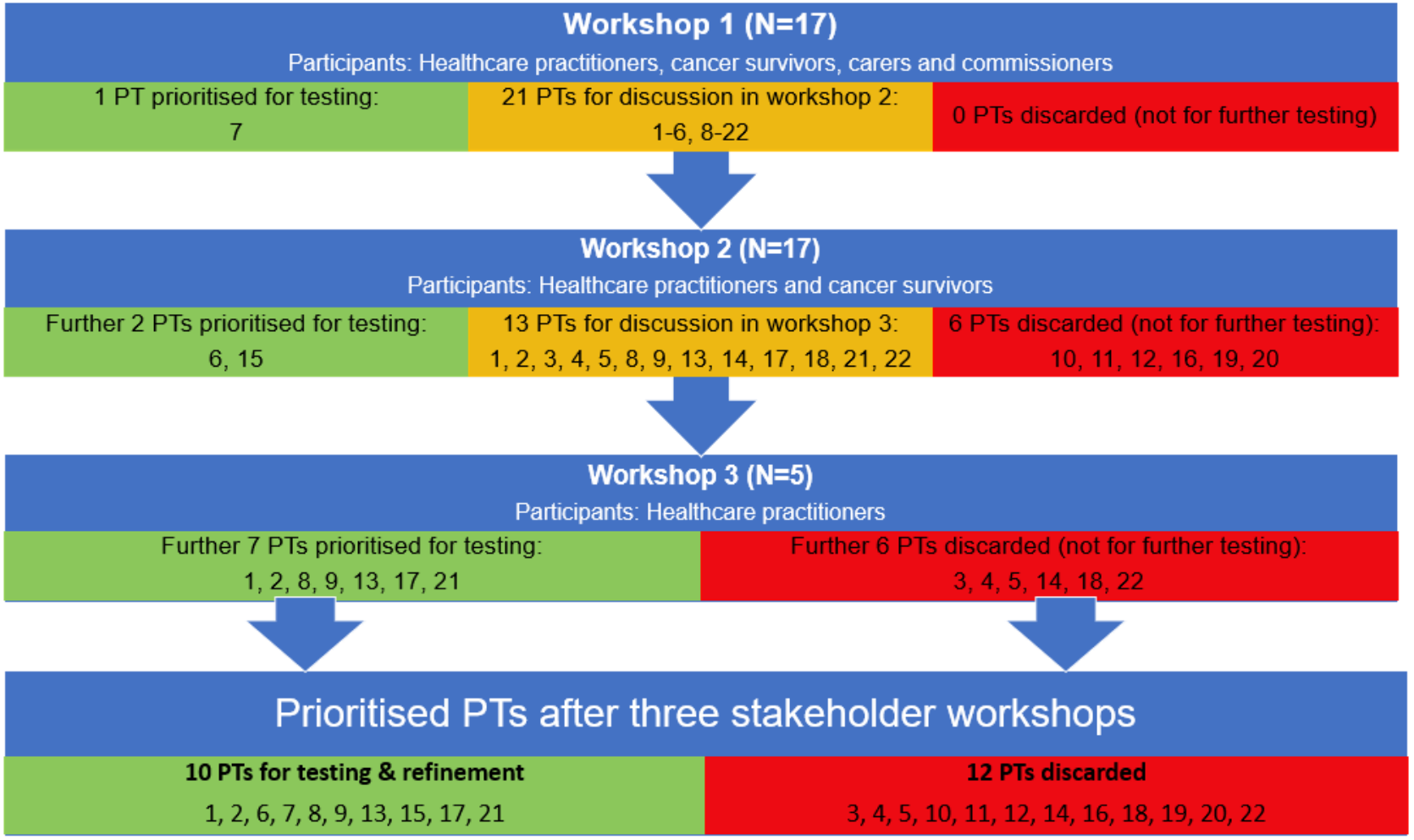

Figure 14: Prioritisation of the ten programme theories (PTs) taken forward for testing in the realist review across three stakeholder workshops

4.6.2 Evidence searches – published literature and practitioner surveys

Published literature

Figure 15 provides the flow of studies from the 708 titles screened, the 58 full text papers reviewed, through to the 20 papers included. Table 13 describes the characteristics of the included papers from the published literature. Eight of the reported studies were conducted in the USA [186-193], three each in the UK [194-196] and the Netherlands [197-199] and two each in Canada [200, 201] and Australia [202, 203]. The remaining studies were conducted in Singapore [204] and Denmark [205]. Various study designs were used, including randomised controlled trials [187, 190, 195, 202, 205], cross-sectional studies [188, 189, 196], reviews [192, 193, 203], and qualitative studies [186, 204].

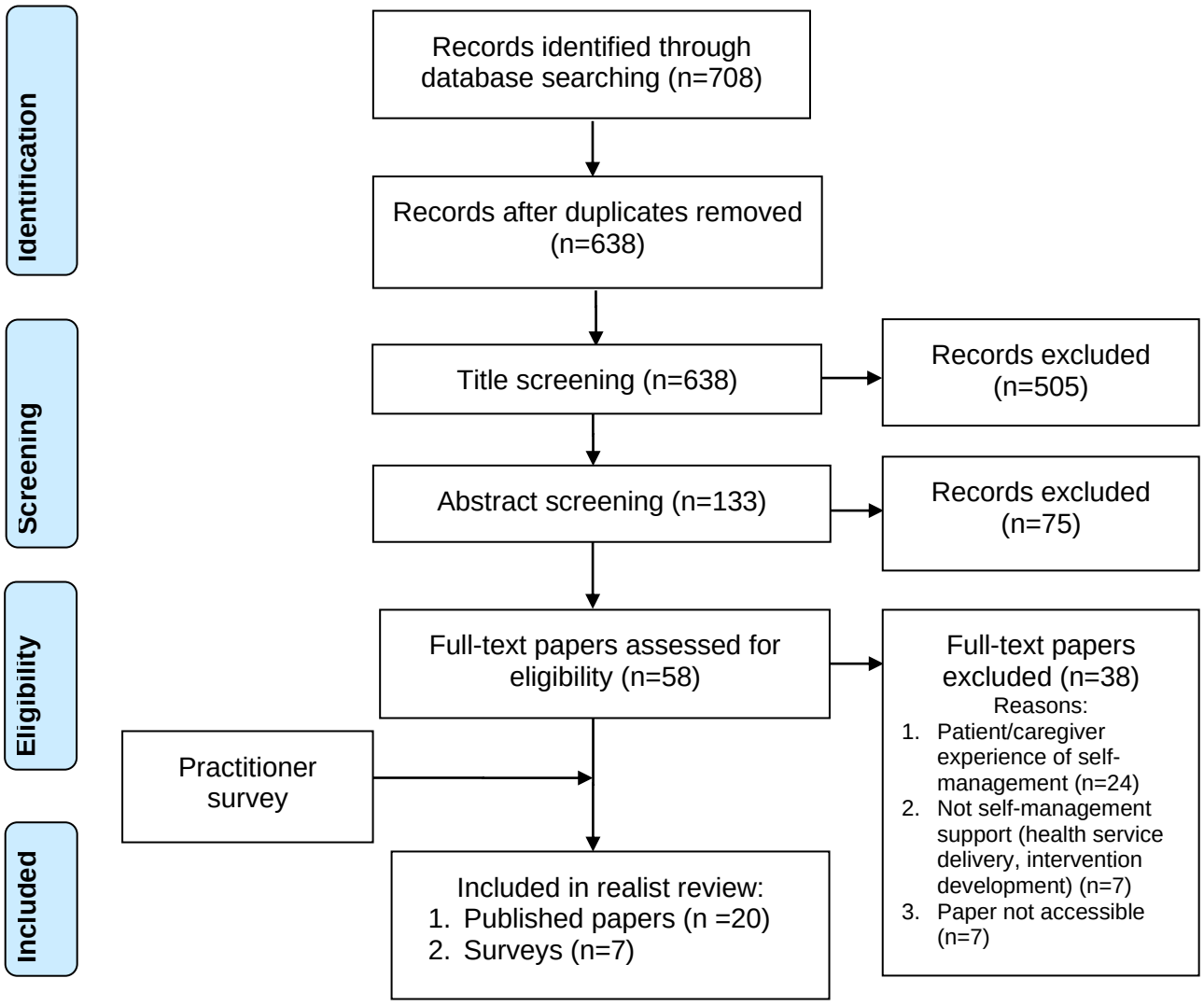

Figure 15: PRISMA flow diagram of included papers and practitioner surveys for the realist review

Table 13: Characteristics of published papers included in the realist review (n=20)

First author (year)	Country	Study design	Study setting	Study population (N)	Practitioners involved	Patient cancer type	Patient age (years)	Intervention	Outcomes
Chan (2017) **[204]**	Singapore	Qualitative – focus groups	Community pharmacies, GP practices	HCP: N=16	General practitioners, community pharmacists	Breast cancer	NR	Survivorship shared care model, including survivorship care plans.	Barriers and facilitators to survivorship shared care model.
Hochstenbach (2017) **[197]**	The Netherlands	Intervention development	Outpatient cancer pain clinic	NR	Nurses, pharmacists, physicians, researchers	NR	NR	NA	Development of a nursing self-management support eHealth intervention.
Reese (2017) **[186]**	USA	Qualitative – focus groups & interviews	Hospital outpatient cancer clinics	Patients: N=28 HCP: N=11	Oncologists, Advanced practice nurse	Breast cancer	NR	Patient-provider communication about sexual concerns.	Communication experiences, needs and preferences.
Mayer (2016) **[187]**	USA	Pilot RCT	Hospital	Patients: N=37 HCP: N=34	Hospital nurse, primary care providers	Multiple: breast, colon, lung, Hodgkin's lymphoma, head & neck, pancreatic, ovarian	≥ 21 years Mean (SD): 56.8 (11)	Control: SCP. Intervention: SCP plus primary care provider visit.	HCP confidence in survivorship information and expectations for cancer survivorship care.
Rosenberg (2016) **[188]**	USA	Cross-sectional study	Hospital outpatient cancer clinic	Patients: N=1615	Oncology nurse, oncologists	Multiple: breast, gynaecological, colorectal, prostate, melanoma	Mean: 57 Range: 21-98	Treatment summary, SCP, risk adapted visit and education.	Improved communication and symptom reporting between patient and HCP.
Arora (2009)	USA	Cross-	State-wide	Patients:	Physicians	Leukaemia,	Mean	Nil – routine	HCP

[189]		sectional study	patient experience of cancer care study	N=623	involved with follow-up care: primary care and hospital oncologists, haematologists, or other specialists	colorectal or bladder cancers	(SD): 62.6 (12.9)	follow-up care.	communication style and survivor quality of life.
Stacey (2016) **[201]**	Canada	Case study	Hospital outpatient cancer clinics	HCP: Case 1: N=31 Case 2: N=47 Case 3: N=41	Nurses, managers and educators	NR	NR	Symptom protocols for providing telephone-based support.	Implementation and sustainable use of evidence-informed protocols.
Campion-Smith (2014) **[194]**	UK	Intervention development	Primary care	HCP: N=10	Practice nurse	NR	NR	Cancer education course.	Preparation of primary care workforce to support people affected by cancer.
Stanciu (2019) **[195]**	UK	Feasibility RCT	District general hospital	Patients Control: N=47 Intervention: N=48	Research nurse	Prostate cancer	Control: 85% (n=40) > 65 Intervention: 81% (n=39) > 65	Control: Usual care. Intervention: Usual care + holistic needs assessment with nurse + follow-up appointments.	Recruitment rate, attrition rate, rate of completion of outcome measures (patient reported measures: physical and psychological symptoms, confidence in managing own health, supportive care needs and general health

									& quality of life.
Jefford (2014) **[203]**	Australia	Review paper	NA	NA	Oncologists, primary care physicians, nurses	Breast cancer	NR	Models of post treatment care.	Patient experiences post treatment and cancer survivorship models of care.
Ratcliff (2018) **[190]**	USA	RCT	Integrated/cancer care settings	HCP, national and advocacy group leads: N=33	Nurses, social workers, counsellors, doctors	Lung cancer	NR	CareSTEPS - Psychosocial intervention targeting caregivers of people with lung cancer.	Caregiver needs, resources, integrating care for caregivers and potential care models.
Melissant (2018) **[198]**	The Netherlands	Feasibility study	Hospitals	Patients: N=101	Oncology nurses	Breast cancer	Mean (SD): 56 (12)	Oncokompas – web-based self-management application - breast cancer	Patient activation and physician-patient interaction.
Bergholdt (2012) **[205]**	Denmark	RCT	General hospital GP practices	Control Patients: N=469 GP practice: N=1090 Intervention Patients: N=486 GP Practice: N=1091	Cancer nurses, GP	Breast cancer, colorectal cancer, Melanoma, Lung cancer, Prostate cancer	Mean: 62.5 Range: 21-91	Control: Usual care. Intervention: Usual care + Patient interview about rehabilitation needs, GP provided information about patient needs and encouraged to contact patient.	GP proactivity to contact patient to facilitate rehabilitation process, patient participation in rehabilitation activities.
Maliski (2004) **[191]**	USA	Descriptive retrospective record	Statewide free prostate cancer treatment	Patients: N=40 HCP: N=7	Nurses	Prostate cancer	15% (n=6) ≥ 65	Nurse-managed care co-ordination	Role of nurse case manager.

		review	programme (IMPACT – Improving access, counselling and treatment)					for patients in IMPACT programme.	
Spencer (2016) **[192]**	USA	Systematic review	NA	N=15 studies included	Nurses, dieticians	Any	NR	Motivational interviewing	Efficacy of motivational interviewing to address lifestyle behaviours and psychosocial needs of cancer patients and survivors.
Duman-Lubberding (2016) **[199]**	The Netherlands	Feasibility study	Hospitals	Patients: N=68	Oncology nurses	Head & neck cancers	Mean (SD): 59.05 (9.85) Min. 25 Max. 77	Oncokompas – web-based self-management application – head & neck cancer	Adoption and usage of web-application and patient satisfaction scores.
Faithfull (2016) **[196]**	UK	Cross-sectional study	Primary and secondary care	HCP: N=618	Oncology nurses, community nurses, allied health professionals	NR	NR	Nil – routine care.	Self-reported competence in long-term care provision for adult cancer survivors.
Tish Knobf (2013) **[193]**	USA	Review paper	NA	NA	Oncology nurses	Any	NR	NA	Informational and support needs of people with cancer and role of oncology nurses in delivery of high-quality

									patient-centred cancer care
Wiljer (2010) **[200]**	Canada	Pilot pre/post-test study	Hospital	Patient: N=40	NR	Breast cancer	15% (n=6) > 60	Survivorship consult – a one-hour template-guided reflective interview to discuss patients' physical, psychological, spiritual & social needs.	Patient self-efficacy to manage survivorship care.
Taylor (2019) **[202]**	Australia	Pilot RCT	Tertiary cancer centre	Patients: N=60 (1:1 intervention: control)	Survivorship cancer nurse	Lymphoma	Control: 37% (n=11) ≥ 60 Intervention: 33% (n=10) ≥ 60	Control: Usual care. Intervention: Usual care + nurse-led survivorship clinic (consultation, SCP, treatment summary and a resource pack of tailored information, support and resources)	Impact of nurse-led model on tailoring supportive care to lymphoma patients.

HCP = Healthcare professional; NA = not applicable; NR = not reported; RCT = randomised control trial; SCP = survivorship care plan

Eleven published studies (55%) evaluated interventions which used structured approaches such as using survivorship care plans, holistic needs assessment or symptom management protocols, by healthcare practitioners to support identification of individual patient needs post cancer treatment [187, 188, 195, 198-202, 204, 205] or carer needs in supporting someone post cancer treatment [190]. Three studies described the role of practitioner communication style in influencing patient behaviour change [186, 189, 192], one study described an education programme to build nurse knowledge and skills to support cancer survivors [194], and one described the impact of support from a dedicated nurse care co-ordinator in enhancing patient self-efficacy [191]. Interventions were delivered in hospital settings in half of the studies and involved cancer specialists such as oncologists and cancer nurses. Nine studies reported self-management support interventions for patients diagnosed with a solid cancer, e.g., breast [186, 198, 200, 203, 204], lung [190], prostate [191, 195], and head and neck [199] cancers. Six studies reported interventions for patients with any type of solid or haematological cancer [187-189, 192, 193, 205] and one study reported a self-management support intervention for patients with lymphoma [202].

Practitioner surveys

A summary of the intervention characteristics from the practitioner survey can be found in Table 14. Seven practitioners from the UK completed the survey. Six interventions were described, with three each delivered in community pharmacy [survey3, survey5 and survey8], and hospital settings [survey2, survey4 and survey7]. One response summarised a qualitative study, which explored the role and scope of community pharmacists in supporting breast cancer survivors, but no intervention was described. All interventions involved educating practitioners to facilitate the delivery of the self-management support intervention.

Table 14: Characteristics of interventions for practitioner surveys included in the realist review (n=7)

Survey no.	Country	Study design	Study setting	Practitioners involved in intervention delivery	Survivor cancer diagnosis	Intervention	Outcomes
2	UK	Feasibility study	Hospital	Oncologist, specialist nurses, researchers, other – computer consultants, commissioners	Lung cancer	Practitioner training about how patients can access and use an App (*iEXHALE*) to facilitate self-management of symptoms through exercise	Practitioner-related: NR Patient related: Ease of use of App, navigation and value in daily life
3	UK	Feasibility study	Community pharmacy	Pharmacy professionals e.g., pharmacists, pharmacy technicians, assistants, etc.	Prostate cancer	Community pharmacy teams were trained to deliver a health assessment including fitness, strength and anthropometric measures. Training included consultation skills and cardiovascular health.	Practitioners and patients: Feasibility and acceptability of intervention
4	UK	NA – Intervention development	Any chemotherapy administration service – mainly secondary care setting	Oncologists, nurses, pharmacists	All people treated with chemotherapy	Video to guide practitioners on the effective use of the record with patients. The video explains the purpose of the record, includes guidance to support self-management and how practitioners can order free copies of the record called *Your Cancer Treatment Record*	Practitioner-related: Ease of use of the record in routine practice Patient-related: Acceptability and usefulness of the record
5	UK	NR	Community pharmacy	Pharmacists	NR	Training pharmacists to deliver patient education aimed at empowering patients to self-management	Practitioner-related: Satisfaction of training Patient-related: Improve confidence and knowledge about how to care for

							themselves and access to appropriate healthcare services.
6	UK	Qualitative study	Community pharmacy	NA	Breast cancer	NA	Exploration of the role and scope of the community pharmacist in supporting breast cancer survivors
7	UK	Proof of concept randomised control trial	Hospital (12 sites)	Hospital team caring for patients, research team, e.g., research nurses and clinical trial officers	All	Randomisation in a 1:1 ratio to receive either the *RESTORE* online intervention or a leaflet comparator developed by Macmillan Cancer Backup, *Coping with Fatigue* Training was offered to practitioners to support their role in the study, as follows: (1) Hospital care team – directing eligible patients to the research team. (2) Research team – screening patients for inclusion, documenting eligibility/ willingness to participate or ineligible and reason for declining where possible. Giving eligible/ willing patients a letter of invitation, information sheet and reply slip and instructions for completing reply slip.	Practitioner-related: NR Patient-related: Feasibility and acceptability, change in self-efficacy to manage cancer-related fatigue
8	UK	NR	Community pharmacy (10 sites)	Pharmacists	All	Training provided to 10 community pharmacy teams to deliver the intervention *Not Normal*	Practitioner-related: Enhance community pharmacist's knowledge of and confidence in recognising red flag cancer

		for You? aimed at identifying patients with 'red flag' cancer symptoms and encouraging them to see their GP.	symptoms. Patient-related: Overcoming barriers to self-referral to GPs

NA = not applicable; NR = not reported

4.6.3 Refinement and production of the final programme theories and corresponding Context-Mechanism-Outcome Configurations (CMOCs)

Table 15 illustrates the transition from ten initial PTs to the final five PTs; these are presented below with their corresponding CMOCs and TDF domains. Illustrative quotes supporting development of the PTs are included in Appendix I.

CMOC1: Practitioners are equipped with the knowledge to enable them to support people to self-manage

Programme theory: If practitioners have the knowledge to identify and manage treatment consequences and navigate the care pathway, including processes for escalating concerns (C), then they will engage in supporting patients to self-manage (O) because of increased practitioner confidence (M). TDF domain: Knowledge

Initially five separate PTs included aspects of practitioner knowledge: PT1 was about knowledge of the cancer care pathway, PT2 was about knowledge of consequences of cancer treatment, PT4 referred to practitioner confidence in their knowledge and skills, and two PTs related to practitioner knowledge about processes for escalating patient safety concerns (PT6 and 10). Reflection and discussion among the review team, based on the evidence indicating that confidence was interlinked with knowledge, resulted in merging these five PTs into CMOC1.

Practitioners who lacked knowledge about how to manage cancer treatment related concerns were reluctant to engage patients in conversations about their concerns or to make referrals to other appropriate practitioners or services. This was due to lack of practitioner confidence [186, 197]. Practitioner knowledge about survivorship care and management of cancer treatment-related consequences may be increased through providing training [194,

196, 200, 203] and using standardised tools, e.g., treatment protocols [201], care pathways [204] or care plans [187, 188, 191, 196, 203, 204]. Increased knowledge raised practitioner awareness of treatment consequences and increased confidence in managing them; it also increased patient confidence in the ability of the practitioner to support them [186, 194, 196, 200, 203] [survey3]. However, increased practitioner knowledge may not lead to improved patient support if the practitioner lacked the confidence to integrate the new knowledge and information into a patient management plan [188]. Further, training and assessment of how to undertake person-centred discussions gave practitioners the confidence to engage in consultations with patients [192, 194]. Two studies reported to undertake person-centred discussions using motivational interviewing techniques [192, 194], are discussed in CMOC2 below.

Practitioner reflections during training enhanced understanding of new knowledge and recalling information. After training, support from senior practitioners was important to assess the application of knowledge in clinical practice [194, 204].

Table 15: Prioritised initial programme theories for testing, refined theories during evidence selection and appraisal and final programme theories after data synthesis

Original PT no.	New PT no.	Initial programme theory	Refined programme theory (Expressed as If … Then statements)	Final programme theory (Expressed as If … Then … Because statements) *[TDF Domain]*
1	**1**	Practitioners will be effective in supporting patients to self-manage if the practitioner has the required knowledge about the cancer pathway.	**If** a practitioner is confident that they have the required knowledge and skills about the cancer pathway, **then** they will engage in supporting patients to self-manage	**If** practitioners have the knowledge to identify and manage treatment consequences and navigate the care pathway, including processes for escalating concerns, **then** they will engage in supporting patients to self-manage **because** of increased practitioner confidence. *[Knowledge]*
2	**2**	Practitioners will correctly identify and signpost patients to self-manage if the practitioner has the required knowledge about the consequences of anti-cancer treatment.	**If** practitioners have the required knowledge about the consequences of cancer treatment, **then** practitioners will correctly identify and signpost patients to self-manage.	**Discarded – merged with final PT1**
6	**3**	Self-management support is more likely to be successful if the primary care team are united in their vision of how it should be achieved.	**If** the primary and secondary care team are united in their vision of how self-management support should be achieved, **then** it is more likely to be successful.	**If** practitioners and patients are united in their expectations and understanding of their respective roles in the care pathway, **then** they will engage in discussions about self-management **because** of a sense of mutual trust and shared responsibility. *[Social/professional role & identity]*
7	**4**	If a practitioner is confident that they have the required knowledge and skills, then they are more likely to engage patients and carers in discussions about self-management.	**Combined with refined PT 1**	NA
8	**5**	If a practitioner feels that signposting patients to self-manage can be integrated into their current role, they are more likely to try doing it.	**If** a practitioner feels that signposting patients to self-manage can be integrated into their current role, **then** they are more likely to try doing it.	**Discarded – addressed by final PT7b**
9	**6**	If a practitioner believes that the self-management package is safe, then they will be more likely to encourage	**If** a practitioner believes that the self-management intervention for patients is safe, **then** they will be more likely to	**Discarded – incorporated in final PT1**

		patients to engage with it.	encourage patients to engage with it.	
13	**7**	If organisations work with practitioners to integrate self-management into routine practice, then practitioners are more likely to engage with it.	**Split into two** **7a** - **If** organisations use strategies to endorse interventions, **then** practitioners are more likely to engage with self-management support interventions. **7b** - **If** systems are configured to integrate interventions into routine practice, **then** the intervention is more likely to be sustainable.	7a - **If** organisations use strategies to endorse self-management interventions, **then** practitioners are more likely to engage with them **because** practitioners perceive those interventions are a priority in the organisation. ***[Intention]*** 7b - **If** systems are configured to integrate self-management interventions into routine practice, **then** interventions are more likely to be sustainable **because** of ease of delivery. ***[Environmental context & resources]***
15	**8**	If systems are organised to encourage and prioritise self-management then this will more likely lead to practitioners feeling supported and equipped to engage in self-management support, resulting in self-management support becoming part of the culture of care.	**Discarded – incorporated into refined PT 7b**	NA
17	**9**	Additional funding is required to enable capacity to be built into the team for practitioners to deliver this new role of supporting self-management.	**Discarded – incorporated into refined PT 7a**	NA
21	**10**	Decision tools such as a traffic light system for when patients should seek hospital advice will reduce anxiety for practitioners arising from the fear that an emergency situation may be missed.	**If** decision tools (such as a traffic light system) for when patients should seek hospital advice are available, **then** practitioner anxiety arising from the fear that an emergency situation may be missed will be reduced.	**Discard – incorporated into final PT1**
NA	**11**	NA	**NEW programme theory** **If** practitioners have the knowledge and skills to engage patients in the consultation, **then** they are more likely to get patients to self-manage.	**If** practitioners have the necessary consultation skills, **then** they are more likely to engage patients in discussions about self-management where patients feel part of the decision-making process **because** of mutual trust between

practitioners and patients.

[Skills]

PT Programme Theory; NA Not Applicable; TDF Theoretical Domains Framework

CMOC2: Practitioners have appropriate consultation skills to engage patients in discussions about self-management

Programme theory: If practitioners have the necessary consultation skills (C), then they are more likely to engage patients in discussions about self-management where patients feel part of the decision-making process (O) because of mutual trust between practitioners and patients (M). TDF domain: Skills

Several papers described how the communication style adopted by practitioners influenced patient interactions. A new PT related to practitioner consultations with patients was therefore developed.

The approaches reported to help practitioners engage patients in discussions during consultations were motivational interviewing and using structured tools, such as, a survivorship care plan. Using motivational interviewing techniques empowered practitioners to use a person-centred approach during consultations [192, 194]. Skills used by practitioners to effectively engage cancer survivors in discussions involved active listening [190, 191, 193], giving patients clear messages [189, 193, 205], purposeful questioning, understanding patient preferences, reinforcing patient capabilities and identifying any actions or resources needed to enable self-management [191]. Consultations delivered by trained existing practitioners e.g., nurses or dieticians, were as effective as those delivered by counsellors specifically hired to deliver motivational interviewing interventions. Further, consultations using motivational interviewing techniques delivered over the telephone were as effective as in-person sessions and offered improved feasibility in busy clinical settings [192]. Equipping practitioners with skills to use tools such as care plans and treatment protocols led to a standardised approach to consultations [201]. However, the use of standardised care plans may not facilitate personalisation of consultations if practitioners

perceive them to be inflexible [204]. Furthermore, practitioners may find it challenging to incorporate protocols into routine care or consultations if they are perceived to be too complex [201].

The setting of the consultation influenced how practitioners engaged patients in discussions. Consultations that took place in non-clinical settings allowed practitioners to explore patient concerns and develop shared solutions in a relaxed environment, with no time pressures or competing demands [195]. Adopting a collaborative communication style allowed practitioners to improve their interactions with patients, thereby building trust and positive practitioner-patient relationships [186, 191]. Improved trust enabled practitioners to effectively address cancer treatment-related consequences reported by patients [189, 193, 205] and improved care satisfaction [186].

CMOC3: Patients and practitioners have shared understanding and expectations of their roles in self-management

Programme theory: If practitioners and patients are united in their expectations and understanding of their respective roles in the care pathway (C), then they will engage in discussions about self-management (O) because of a sense of shared responsibility (M).
TDF domain: Social/professional role and identity

Initially PT3 only included primary care practitioners, as the preliminary search suggested that primary care practitioners were unclear about their role in supporting cancer survivors to self-manage. However, practitioners from all care settings were incorporated as the review progressed, because the evidence indicated that the need for greater role clarity regarding self-management support also extended to hospital practitioners. Additionally, PT3 was further refined to include the patient role as the evidence indicated that practitioner engagement with self-management support was interlinked with patient understanding and expectations about self-management. There were two aspects to CMOC3 – understanding

and expectations between practitioners and patients and understanding and expectations between practitioners across care settings.

When practitioners had a clear understanding of their role and responsibility, they proactively interacted with cancer survivors to assess their needs and provide information and support or make referrals to other sources if needed [194]. Patients who understood the potential long-term impact of cancer and its treatment and who had information about local survivor-specific services, were better able to cope and adjust to life post-treatment and more likely to seek support for self-management [193, 204]. When expectations were misaligned, practitioners and patients were less inclined to engage in discussions about self-management [190, 204].

Sharing care/management plans between practitioners from secondary and primary care facilitated effective care continuity and co-ordination. Sharing plans resulted in improved practitioner knowledge of treatment consequences, and how to monitor consequences led to improved practitioner understanding of their role and responsibilities in relation to supporting self-management [187, 193, 203]. Providing joint training for practitioners in secondary and primary care settings [194, 203], co-location of practitioners [190], and care plans developed in secondary care that included useful information for practitioners in primary care [196, 204] facilitated a shared understanding of practitioner roles and responsibilities, and managed expectations related to supporting self-management.

CMOC4: Organisational strategies enable practitioners to deliver self-management support interventions

Programme theory: If organisations use strategies to strengthen practitioners' intention to deliver self-management support interventions (C), then practitioners are more likely to engage with the interventions (O) because they perceive them as a priority for the organisation (M).

TDF domain: Intention

At the start of the review the initial PT7 presented the role of organisations in facilitating practitioners to deliver self-management support interventions. Evidence indicated that the way health systems are arranged influence practitioner engagement with self-management support interventions. Therefore, the initial PT7 was split into CMOC4 and CMOC5 to reflect the different roles played by organisations (final PT7a) and health systems (final PT7b). Discussion among the review team also led to discarding PT9, which related to the requirement of additional funding to enable capacity building to deliver self-management support, as organisational funding was embedded into CMOC4.

A wide range of environmental changes introduced by organisations were intended to motivate or incentivise practitioners to deliver self-management support.
Strategies involved providing adequate resources for preparing, planning and delivering interventions, such as introducing clinics specifically for supporting cancer survivors post treatment [188, 204], providing practitioners with guidelines, tools and training to support practitioners during consultations [194, 201], employing dedicated practitioners, such as oncology nurses or counsellors to deliver interventions [190, 195, 201], and funding [190]. Funding was important to support intervention delivery; however, a fee-for-service funding model was discouraged in one study as there was a risk that services offered may not be relevant to patients. It was suggested that practitioners may be tempted to offer extra or unnecessary services because service provision was linked to practitioner salary [190].

Managers who provided leadership through endorsing interventions and who shared their expectations for practitioners to deliver interventions influenced whether practitioners prioritised delivery of self-management support [190, 194, 201]. Organisations that incorporated intervention evaluation through metrics about practitioner performance or

through monitoring patient outcomes were able to demonstrate the value of interventions and further promote their delivery within organisations [190, 194].

Organisational strategies were further shown to increase practitioner confidence in and engagement with delivering self-management support interventions [204] and supported integration and sustainability of interventions into routine care [188, 190, 201]. Shorter, modifiable interventions, that could be delivered face-to-face or technology-assisted, were preferred by practitioners. Flexibility of intervention delivery was important for practitioners to facilitate appropriate use of healthcare resources [190] [survey2, survey3, survey5, survey7].

CMOC5: Health systems are configured to integrate self-management support interventions into routine care

Programme theory: If systems are configured to integrate self-management support interventions into routine practice (C), then interventions are more likely to be sustainable (O) because of ease of delivery (M). TDF domain: Environmental context and resources

This CMOC resulted from splitting PT7, which related to the role of organisations in facilitating practitioners to deliver self-management support interventions, to focus on how the arrangement of the health system influences sustainable delivery of self-management support interventions. Two overlapping PTs were dismissed: PT8 related to the health system being arranged to encourage and prioritise routine self-management support and PT5 related to the health system infrastructure facilitating integration of sign-posting into routine care.

Interventions designed to meet the needs of local services facilitated integration into routine care [190] and those with suitable referral pathways and processes facilitated clinical

discussions [186]. Communication and care co-ordination between practitioners from different care settings were facilitated through the use of tools, such as care plans and guidelines [187, 188, 191, 193, 196, 203, 204].

Having dedicated resources to implement and deliver interventions was shown to be important not only for organisations, as shown in CMOC4, but also for the healthcare system. For example, introducing nurses dedicated to supporting self-management, led to increased service capacity without compromising care delivery in other parts of the system [195, 201, 204].

Shared care models facilitated integration of interventions into routine practice by providing a mechanism whereby senior managers formally evaluated the organisational infrastructure to deliver the intervention and introduced necessary supportive changes [190, 204]. Defining practitioner roles and responsibilities was key to prevent misunderstanding about who was responsible for patient care [197, 204].

4.7 Discussion

This review set out to understand, using a theoretical framework, the influences involved in facilitating practitioners to provide routine self-management support to cancer survivors. Five interdependent PTs were developed from the evidence. They highlight the importance of healthcare practitioners having sufficient knowledge and skills to give them the confidence to engage patients in discussions about self-management. Healthcare practitioners and patients need to be clear about their respective roles in self-management by creating a sense of shared responsibility. Finally, organisations and the wider health system need to put in place the necessary resources and processes to create an environment where self-management support is perceived as an organisational priority, facilitating integration into routine care.

Some of the key contextual influences identified in this review have been described elsewhere. For example, a call to action for embedding self-management support in routine cancer care [75] highlighted that practitioners need training to improve their knowledge and skills, and practitioners and cancer survivors need better understanding of their roles and responsibilities to foster a partnership approach. While developing knowledge and skills are the first step towards reframing practitioner roles and responsibilities, providing organisational resources alongside changes to the design of the wider health system are needed to integrate self-management support into cancer care.

Organisational support was crucial for allowing practitioners to integrate self-management support into the routine care of people with chronic conditions [206]. However, evidence for organisational strategies to effectively embed self-management support in routine cancer care is limited. A recent mixed-method study of self-management support readiness in Canadian ambulatory cancer centres noted that organisations could facilitate practitioners to deliver self-management support through strong leadership, appointing champions, prioritising self-management in the organisation, and introducing processes for feedback and tools for monitoring quality of care [86]. The present realist review found that alongside senior leader/manager support, funding, monitoring and feedback, the design of the intervention was important for practitioners to perceive self-management support as a priority for the organisation. Interventions should not only meet local needs but also need to be adaptable to practitioner circumstances. Self-management support interventions for cancer survivors emphasise the need to depart from a ‘one-size fits all’ approach towards more personalised support to meet individual patient needs [20]. Interestingly, the present review found that interventions to facilitate practitioners to provide self-management support may also need to be tailored to meet the unique needs of practitioners, which may depend on available resources, such as, time and space. An understanding of the local context and

practitioner needs will thus be critical before developing and designing self-management support interventions targeted at practitioners.

Healthcare organisational culture and social norms are considered key contextual factors that influence implementation of healthcare practices, service improvements and patient outcomes [207, 208], but are notoriously difficult to assess and manage [209]. Organisational culture is the shared ways of thinking, feeling and behaving in organisations [209]. Social norms, the shared values, beliefs and attitudes that influences behaviour, lie at the heart of influencing organisational culture [210]. Unsurprisingly, no evidence was found in the included studies for the influence of organisational culture and social norms on implementing or delivering self-management support. Self-management support interventions will be implemented and delivered in the context of the underlying cultural and social norms within the organisation. Understanding these cultural and social influences may provide deeper insights into how self-management support interventions could be shaped to improve cancer survivor outcomes.

The current literature suggests that successful implementation of self-management support in cancer survivors will require a 'whole system' change [72, 75, 76, 96, 211]. However, evidence for what system change is needed and how the change can be achieved is lacking. The literature on self-management support in chronic conditions, such as diabetes and asthma, highlight that embedding self-management support is not about adding interventions to existing services [212]. It requires a fundamentally different way of working and the necessary infrastructure to facilitate a shift from focusing on disease management to supporting patients to manage their own health and wellbeing. The present review begins to build the evidence for the role of health systems in facilitating integration of self-management support in routine cancer care. This review found that suitable referral pathways and processes that allow practitioner collaboration across care settings, together with clarification of roles and responsibilities are important. While these findings seem to overlap with the

chronic condition literature, it cannot be assumed that these strategies will be applicable in the cancer setting in exactly the same way, given the complex, multi-faceted and fluctuating nature of cancer [213].

Developing knowledge and skills was shown to influence nurses' confidence, but this did not always result in changes to daily practice due to the complexity of delivering self-management support [116]. Whilst the present review suggests that mutual trust and shared responsibility are crucial mechanisms for enabling patient-centred collaborative interactions between practitioners and patients, studies have highlighted that the current dominance of the traditional model of care hampers effective delivery of self-management support [73, 214, 215]. Similar to the present review's findings, prioritisation of self-management support by organisations has been shown to facilitate delivery by practitioners, but only if there are no other competing priorities [90]. For example, an intervention to enhance self-management support in routine primary care was ineffective as it was not viewed as a priority by practitioners, who were more focused on delivering tasks linked to a pay-for-performance framework [215]. Although the identified five mechanisms have been described in studies related to self-management support in chronic conditions, this study reports on their potential contribution in facilitating practitioners to deliver self-mangement support in the cancer setting. An understanding of the interactions between mechanisms, the outcomes produced and the context may be key to developing successful interventions.

Strengths of this review include combining a realist lens, a relatively new approach to evidence synthesis, with a widely used behavioural framework to deepen understanding of the contextual factors influencing practitioner delivery of self-management support in cancer survivors and their mechanisms. This is the first of its kind. A realist review was chosen to facilitate a structured approach to synthesising heterogenous literature using varying study designs and real-life experiences of practitioners. Additionally, the two approaches complemented each other. The TDF provided a theoretical lens through which to view

contexts and mechanisms, and how they influenced practitioner provision of self-management support. The realist approach allowed interrogation of the relationships between the different contexts, mechanisms and outcomes. Future intervention development studies should explore how the TDF can be used to progress from understanding of contextual and causal mechanisms to guiding selection of behaviour change techniques to designing complex interventions [87] to address identified barriers and enablers.

Limitations include those commonly reported in realist reviews. The included studies provided limited details about the intervention and some information about contexts and potential mechanisms. Broad statements were therefore formulated, which were informed by the TDF and seem to reflect those reported in similar studies exploring practitioner delivery of self-management support [86, 90]. Not all of the published studies focused explicitly on interventions facilitating practitioner provision of self-management support in cancer survivors. Therefore, studies that broadly described interventions for supporting people post cancer treatment were drawn upon and this was combined with practitioner surveys. The practitioner surveys, despite being small in number and focusing exclusively on educational interventions, enriched the understanding of the scope of interventions for facilitating practitioners to deliver self-management support to cancer survivors in the UK. The search strategy used in this review aimed to systematically identify sufficient sources to build and test theory. However, it is possible that relevant literature could have been inadvertently overlooked. Rather than identifying all available documents, it is acceptable for realist reviewers to take a purposive sampling approach which aims to reach conceptual saturation [96]. The quality of the studies was not formally assessed because the traditional hierarchy of evidence is of lesser importance in realist reviews compared to traditional reviews. This review mainly derived evidence from higher income countries. These countries have better health infrastructures and resources compared to lower income countries, which may limit applicability of the findings in these countries.

4.8 Chapter summary

This realist review has identified five interdependent PTs that need addressing to facilitate practitioners to provide routine self-management support to cancer survivors. At the practitioner level, developing knowledge and consultation skills should improve confidence in engaging cancer survivors in discussions about self-management. Also, at the practitioner-patient level, a clear understanding of roles and responsibilities will facilitate a partnership approach to self-management. At the organisational level, prioritising self-management support will provide a top-down incentive for practitioners. Finally, reconfiguration of pathways and processes across the health system will enable sustained delivery of self-management support. A variety of approaches may be employed, such as quality improvement and co-design to operationalise how these PTs could guide the development and implementation of self-management support interventions.

The contribution of this chapter to the development of the logic model is the identification of the determinants for practitioners supporting adult cancer survivors to self-manage, shown in figure 16.

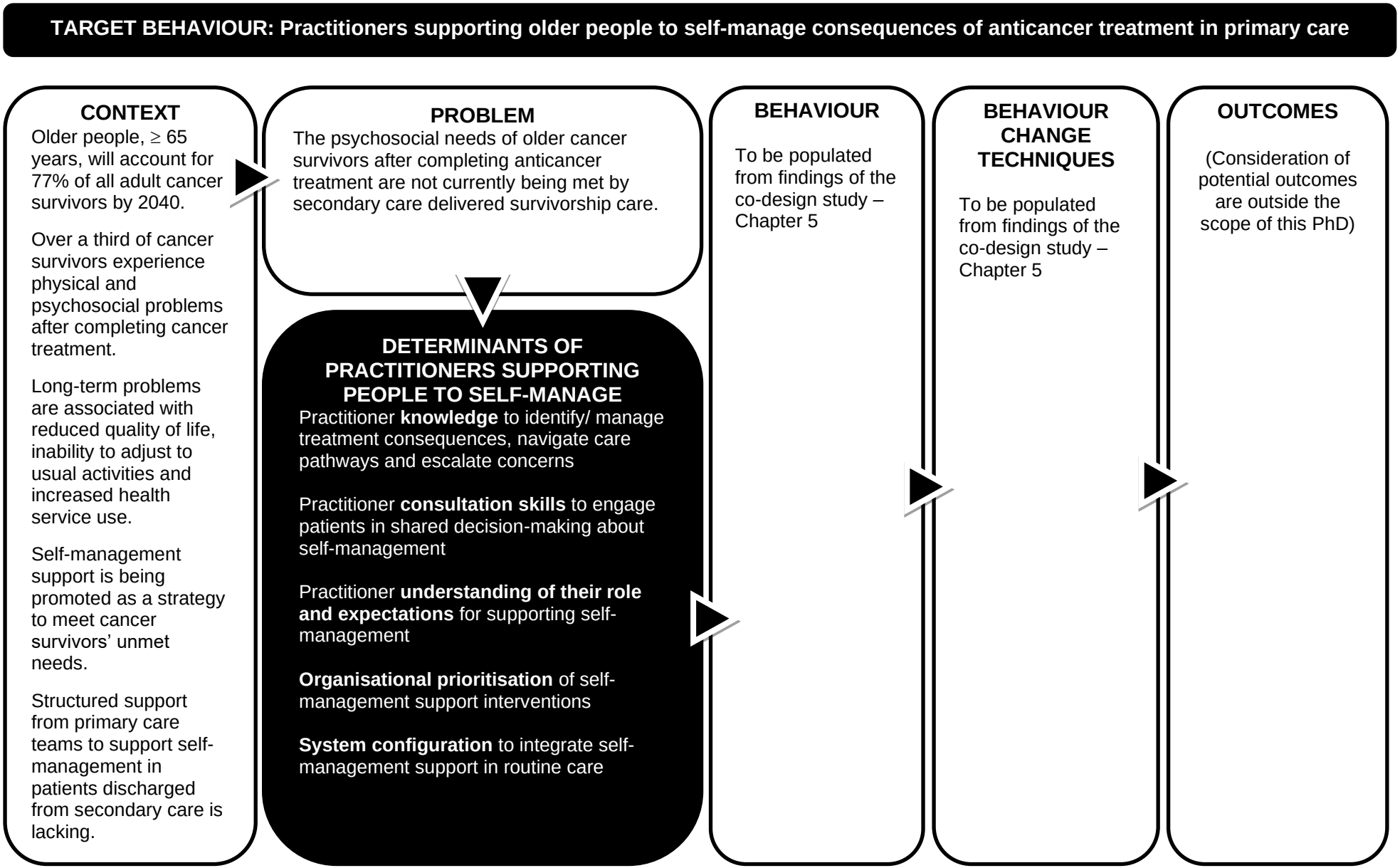

Figure 16: Logic model: contribution of the realist review to identify determinants of practitioners supporting cancer survivors to self-manage

This review makes some notable contributions to the evidence. These are categorised as contribution to the evidence base related to self-management support in adult cancer survivors, identification of future research topics, and methodological advances to realist enquiries.

Building on the evidence about self-management support interventions for cancer survivors:

- This is the first realist theory-driven review undertaken to synthesis existing literature on self-management support interventions targeted at practitioners.
- Five programme theories were identified, with the linked mechanisms and contexts that may help to inform future intervention development.
- Self-management support interventions targeted at practitioners need to be tailored to the requirements of practitioners and the available organisational resources.

Potential topics for future research to address evidence gaps related to self-management support interventions in cancer care:

- There remains a need to explore the association between organisational culture and social norms on delivery of self-management support as part of routine cancer care.
- Further understanding is warranted of the health system-related changes necessary for integrating self-management support in routine cancer care.
- Realist reviews on self-management support interventions targeting cancer survivors are needed to understand the links between contexts, mechanisms and outcomes, and their potential utility in intervention development.

Methodological advancement for realist enquiries:

- Multiple data sources were used in the evidence synthesis, i.e., secondary data from existing published literature on self-management support interventions and empirical

data derived from unpublished interventions via practitioner surveys to enrich understanding of the causal mechanisms involved in generating outcomes in particular contexts.

- The application of the TDF to develop realist programme theories was unique to this study. The TDF has been used in several systematic reviews to facilitate exploration of clinical practice and identify potential intervention strategies to address implementation problems [216, 217]. This is the first realist review to use the TDF to guide programme theory development and refinement.

There remains a need to understand how applicable these findings are to the primary care setting in the NHS in England, as the intervention being planned is bespoke for the NHS.

Chapter 5 reports the experiences of primary care and community pharmacy teams with respect to the barriers and enablers for supporting self-management in cancer survivors, specific to the NHS in England, and compares these experiences to those identified in the realist review (this chapter). Chapter 5 also reports the development and design of an intervention to facilitate practitioners in primary care to support older cancer survivors to self-manage long-term consequences of anticancer treatment.

Chapter 5 Co-designing an intervention to facilitate primary care teams to provide self-management support to older cancer survivors

5.1 Introduction

Chapter 1 described self-management support as a strategy by the NHS to cope with long-term problems arising from anticancer treatment in adult cancer survivors. Chapter 3 built on the evidence by exploring the prevalence of long-term physical, psychological and social consequences of anticancer treatment in older cancer survivors. Chapter 3 also showed that the current service model for the care of older cancer survivors post completion of anticancer treatment is inadequate. In particular, older cancer survivors perceived the services within the NHS secondary care setting as unsatisfactory with respect to providing support for managing the long-term psychosocial problems of anticancer treatment. Additionally, older cancer survivors may need support beyond the usual follow-up period in secondary care.

Primary care teams provide the first point of contact in the NHS healthcare system. Although general practice teams are considered a part of primary care in the NHS, other teams are also included, such as, dentistry, optician and community pharmacy teams [218]. In the present chapter 'primary care teams' refers to practitioners in general practice, such as general practitioners and practice nurses, and community pharmacists. Primary care is promoted as a setting to provide supportive care close to home for cancer survivors [68, 71] and may therefore be the most appropriate setting for addressing the long-term consequences of anticancer treatment.

Chapter 4 described the key barriers and enablers for practitioners delivering self-management support to cancer survivors, derived from a realist review of published and unpublished data and supported by behavioural theory. The realist review included studies

from several countries and included various healthcare practitioners across any healthcare setting. The realist review identified a number of barriers and enablers at practitioner, organisation and health system levels. The present chapter describes the development and co-design of an intervention to facilitate primary care teams in the NHS in England to deliver self-management support to older cancer survivors, that addresses the barriers identified in the realist review that are relevant to the NHS context. This chapter details the iterative co-design of an intervention using the Stanford Design Thinking process.

In addition, the method used to link the co-design process and the findings of the realist review, are described. This involved mapping the identified enablers to the TDF domains and associated behaviour change techniques (BCTs).

5.2 Aim

To co-design an intervention to address the identified barriers to the delivery of self-management support by primary care teams in the English NHS to older cancer survivors.

5.3 Methods

5.3.1 Overview of the co-design process

There is growing consensus that co-designing research may be a mechanism to address the challenges of getting research into practice and for its potential to improve the quality and relevance of the research [219]. Successful implementation of research findings into practice requires a combination of several sources of evidence [220]. Co-design approaches facilitate synthesis of different forms of evidence by guiding stakeholders into creating knowledge that is receptive to real world requirements [221]. Services designed using co-design approaches are more likely to be acceptable to and adopted and sustained by service users and providers [123].

Numerous processes could be used to operationalise the co-design approach, e.g., the Person-Based Approach [125], the Double Diamond process [126], Stanford Design Thinking Process [127] and Experience-based Co-design (EBCD) [128]. The Stanford Design Thinking process, introduced in Chapter 2, was employed for this study.

Design Thinking is a systematic innovative process that prioritises the desires, needs and challenges of service users to gain a deep understanding of a problem in order to develop comprehensive and effective solutions. In healthcare, using Design Thinking in the early phases of intervention development has resulted in improved service user, service provider and community satisfaction. It has also increased efficacy and collaboration during intervention development and has been used as a tool to address health inequities [222, 223]. The process begins with engagement with people most affected by or knowledgeable about a service that needs improving or changing. This is followed by working with diverse stakeholders to synthesise alternative ways of achieving the desired results. A series of critical reviews of the ideas then help to identify the ones that meet the needs of most stakeholders and are cost-effective and feasible to implement. The design process then moves to prototyping and testing, where multiple ideas may be piloted and evaluated in small trials to allow selection of the 'best-fit' solution, which is ready for large scale implementation. The Design Thinking process has five iterative steps: (1) empathise with the end-user, (2) define the problem, (3) ideate a solution, (4) prototype the solution, and (5) test with the end-user [127].

Figure 17 provides an overview of the first three steps of the five-step process for this study. Three online discovery workshops were convened for the *Empathise* step to allow a deep understanding of the barriers and enablers of community pharmacy and general practice teams supporting older people to self-manage long-term problems caused by anticancer treatment. The discovery workshops further sought to identify the necessary practitioner tasks to support people to self-manage. These were followed by three online co-design

workshops with practitioners and service users to *Define* and *Ideate* the intervention design. The final two steps, *Prototype* and *Test*, are planned for a future study which is beyond the scope of this PhD thesis.

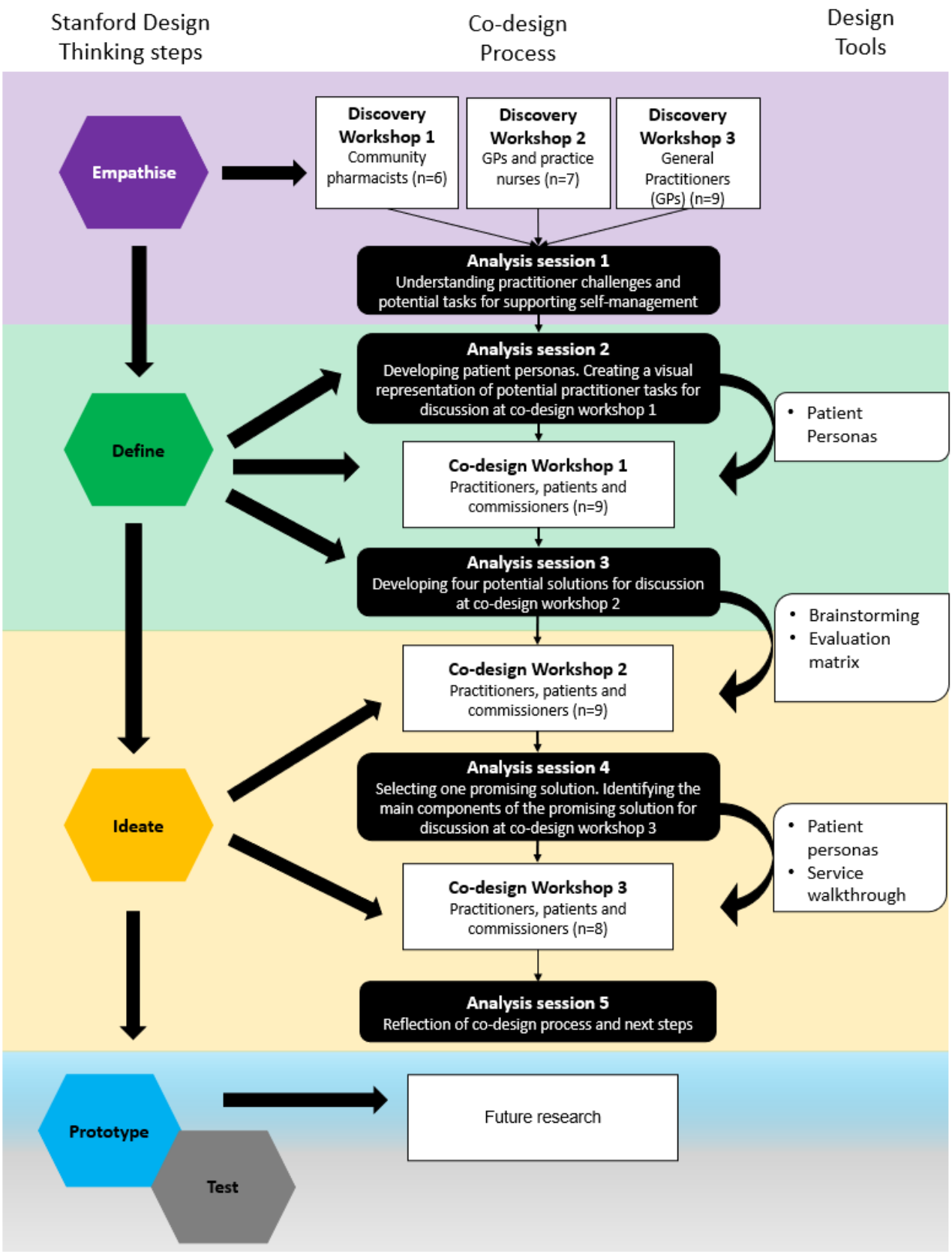

Figure 17: Overview of the co-design process, design thinking steps and design tools used

5.3.2 Ethics approval

Ethical approval for this study was granted by the Health Research Authority (REC reference 20/WS/0163). The ethical approval letter is provided in Appendix J.

5.3.3 Participants

Discovery workshops

Community pharmacists, general practitioners or practice nurses were eligible if they were registered with their respective UK professional regulatory body, and with a minimum of two years clinical experience of which some time must have been spent supporting people living with and beyond cancer. Participants were required to have access to a device and a stable internet connection for the online discussion. Potential participants were identified via four Clinical Research Networks in England (Eastern, East Midlands, Yorkshire and Humber and South London) by distributing a participant information sheet and an online expression of interest form to take part in a 2-hour online discovery workshop. From those that responded, 22 practitioners were selected based on availability to attend one of three discovery workshops and invited to complete an online consent form. Participants were reimbursed for attending the online discovery workshops.

Separate discovery workshops were planned for community pharmacists and general practice participants to get a deep understanding of the challenges faced by each group to engage older people in conversations about self-management of long-term problems caused by anticancer treatment. Keeping the groups separate enabled capitalisation on shared experiences and expectations. Recruitment of 10-12 participants from general practices with a mix of general practitioners and practice nurses with different experiences, and 10 community pharmacists from different services was planned, to allow mapping of the barriers and enablers.

Co-design workshops

The online co-design workshops were open to practitioners who participated in the discovery workshops, additional practitioners identified via the four Clinical Research Networks in England, patients, and cancer services commissioners. These groups were invited to participate to ensure that all relevant stakeholders involved in commissioning, delivering and receiving the proposed intervention were involved in the co-design process.

Potential patients were identified via cancer charities and relevant organisations in the East of England by distributing a participant information sheet and an online expression of interest form to take part in three 2-hour online co-design workshops. Patients were eligible if they were aged 65 or more and had completed treatment for cancer or were on long-term maintenance anticancer treatment. Commissioners were eligible if they were responsible for commissioning cancer services in the East of England. Eligible participants were selected based on a mix of practitioners and non-practitioners and availability to attend three co-design workshops and invited to complete an online consent form. The target was to recruit around 10 participants to ensure representation from each stakeholder group and to allow for small group work, whole group discussion and individual contribution. Participants were reimbursed for attending the online co-design workshops.

Alongside participants, three members of the research team (KK, DB and JT), with expertise in intervention development, behaviour change and co-design, joined the co-design sessions. An additional member of the research team (WH) joined on the analysis sessions after each co-design workshop to discuss and analyse the key insights arising from the workshop and plan subsequent workshops.

5.3.4 Discovery workshops 1-3 – Empathise and Define

Three online discovery workshop discussions, one with community pharmacists and two with mixed groups of general practitioners and practice nurses were convened. At the start of each discovery workshop, results were presented from the Chapter 4 realist review

regarding what works to facilitate practitioners to support patients to self-manage the long-term consequences of cancer treatment and what the barriers are. Participants were asked to discuss the applicability of the findings from the realist review relative to their own experiences and that of others. The topic guide used in the discovery workshops is shown in Appendix K. The topic guide facilitated participant discussion about the key barriers and enablers for delivering self-management support in their practice setting.

The discovery workshop discussions were analysed in two stages by the research team. The first stage involved understanding and summarising the key enablers and barriers faced by community pharmacy and general practice teams in supporting older people to self-manage after completing anticancer treatment. This stage also summarised any similarities and differences between the community pharmacy and practice teams. Understanding and summarising the key challenges by community pharmacy and general practice teams corresponded to the *Empathise* step of the Stanford Design Thinking process. As the data were analysed, the research team were looking to identify the primary care practices, behaviours or tasks that are associated with providing self-management support to older people with cancer. The potential practitioner tasks to target were identified, which corresponded to the *Define* step of the Stanford Design Thinking process. This involved undertaking a directed content analysis of the discovery workshop data and synthesising these with the findings from the realist review.

The second stage of analysis involved planning the first co-design workshop. Data from the discovery workshops were used to inform the preparation of patient personas representing the type of patients likely to benefit from self-management support in community pharmacy and general practice and the barriers they may face. The criteria that guided creation of the patient personas were based on knowledge gained from existing evidence and clinical expertise of the research team and discovery workshop participants, and are presented below:

- Patients will have different types of anticancer treatment with varying duration, side effects and long-term consequences.
- Patients may have been given information or signposted to support by the hospital cancer care team, which may or may not be adequate for the patients' needs.
- Patients may not be able to recognise the symptoms or side effects that require medical input.
- Individual patient circumstances, such as functional/cognitive ability, co-morbid conditions, cultural background and existing support networks, may influence how they engage with self-management.

In addition to the patient personas, a visual representation of the proposed tasks that primary care teams could undertake to support self-management was developed to represent key findings from the *Define* step.

5.3.5 Co-design workshop 1 – Define and Ideate

The first co-design workshop was convened to discuss findings from the discovery workshops and start to co-design the intervention. This workshop sought to prioritise the barriers to supporting self-management to be targeted in the intervention (*Define*) and start to explore potential solutions that will form the intervention components (*Ideate*).

The patient personas, informed by discussions from the discovery workshops and existing evidence, were used to explore what good self-management might look like for patients, who might be supporting them to self-manage, who might be best placed to support self-management, and how, where and when might the patient engage with community pharmacy and general practice teams. The three patient personas developed for the co-design workshops are included in Appendix L.

The potential tasks that primary care teams could undertake to support patients to self-manage, identified during the discovery workshops were presented to participants. Participants were encouraged to draw on their own experiences of either supporting self-management or of self-managing, to ensure that the co-design process was underpinned by real-world practice and experience [127].

The research team met to synthesise the ideas and discussions from the workshop. This involved summarising the key ideas and thoughts generated from the workshop and visually representing these as potential solutions for exploration in the next *Ideate* step at co-design workshop 2.

5.3.6 Co-design workshop 2 – Ideate

The potential solutions developed from co-design workshop 1 were presented to participants to facilitate them to identify the most promising solution to take forward to the next co-design workshop. An evaluation matrix was used to support identification of the most promising solution, using two measures, COMPLEXITY and VALUE [224] (shown in figure 18).

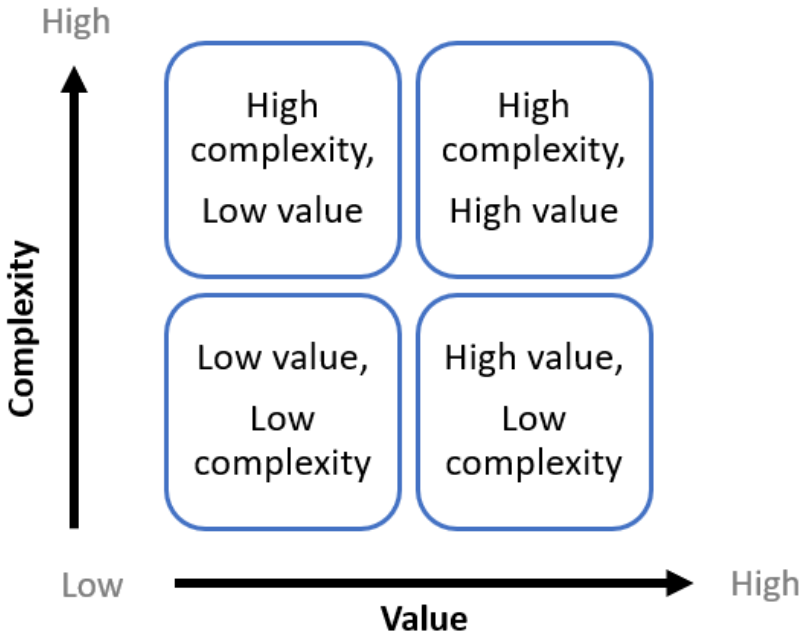

Figure 18: Evaluation matrix used to select a promising solution to facilitate primary care teams to provide self-management support

During the workshop, participants were asked to brainstorm ideas and set the criteria for VALUE and COMPLEXITY in the matrix. Participants were invited to vote on whether each solution generated after the first co-design workshop had high/low VALUE and high/low COMPLEXITY via live polling. This facilitated selection of a solution that provided high value, and low complexity. Participants were then invited to brainstorm ideas about which members of the community pharmacy and general practice teams would be best placed to support delivery of the selected solution.

The research team met after the workshop to further refine the most promising solution selected by co-design workshop 2 participants and to plan the final workshop. Synthesis involved identifying the main components of the selected solution, based on the key thoughts and ideas generated in the workshop. This resulted in an intervention, which was proposed to participants at the third and final co-design workshop. The intervention was called a ‘service pathway’ for ease of participant understanding as it resembled a typical pathway for services delivered in primary care.

5.3.7 Co-design workshop 3 – Ideate

In workshop 3, the patient personas developed in the *Empathise* step were re-used to understand how patients might interact with the different components of the proposed service pathway generated from the solution selected in the previous workshop. How wider primary care teams could engage with the proposed service pathway was also explored.

After the workshop, the research team synthesised the key messages arising from discussions during the workshop. How each component related to existing resources or processes were summarised. This facilitated exploration of the ease of set up and delivery of the new proposed service pathway.

5.3.8 Linking findings of the realist review and the present study to guide intervention development

Developing interventions to change practitioner behaviour typically involves using evidence and theory to: (A) understand the behaviour that needs to change, (B) identify the potential strategies for the behavioural intervention, and (C) identify the intervention contents and options for implementation [85]. Figure 19 illustrates the link between these stages, the realist review and present study.

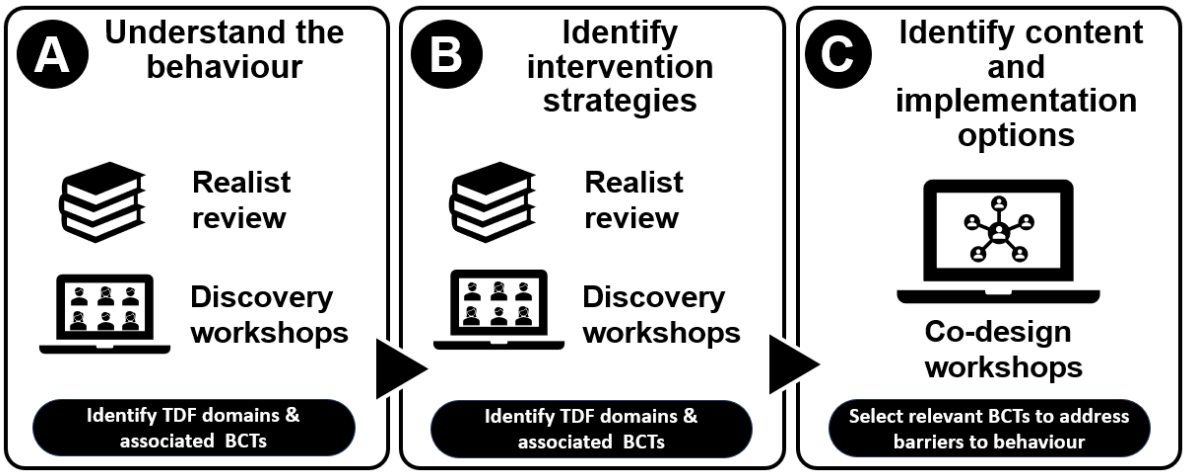

Figure 19: Link between the realist review and discovery and co-design workshops to develop an intervention in primary care to support self-management in older cancer survivors

TDF = Theoretical Domains Framework, BCTs = Behaviour Change Techniques

A. Understand the behaviour

The discovery workshops complemented the realist review findings by providing a better understanding of the barriers and enablers identified in the realist review and whether there were any differences for self-management support delivered in the NHS context. This improved understanding of the barriers and enablers helped to refine mapping to the TDF domains.

B. Identify intervention strategies

The Theory and Techniques tool (TATT) has been developed to aid selection of appropriate BCTs by linking BCTs to mechanisms of action which also align with the domains of the TDF [225]. Each TDF domain has therefore been mapped to several BCTs, which are the active ingredients of the intervention [226, 227]. The TATT is an interactive online resource developed using evidence triangulated from published studies [228] and by expert consensus [229]. The BCTs listed in the TATT are drawn from the BCT Taxonomy (v1) [230], a structured taxonomy of 93 distinct consensually agreed BCTs.

In this study the TATT was used to identify all BCTs linked to the TDF domains for the prioritised barriers identified from the discovery workshops. To narrow down the list of BCTs, the included papers in the realist review were revisited. Where available, practitioner target behaviours and intervention features and delivery modes were extracted and mapped against BCTs linked to the TDF domains of interest. The extracted information was independently checked by two members of the research team (DB and WH) to ensure the selected BCTs were appropriate. The research team had planned to share this focused list of BCTs with the co-design workshop participants. However, as the workshops progressed, the research team felt that it would detract from the natural flow of thought during discussions and hinder idea generation. The list of BCTs was therefore referred to by the research team during workshop synthesis and analysis.

C. Identify content and implementation options

Intervention content and implementation options were identified during the co-design workshops. The most promising of these informed the development of an intervention. The main components of the intervention were mapped to the specific BCTs, identified from the focused list of BCTs, to address the barriers to facilitating practitioners in primary care to deliver self-management support to older cancer survivors.

5.4 Results

5.4.1 Participant characteristics

In total, 22 participants attended the three discovery workshops: community pharmacists (n=6) representing six pharmacies, practice nurse (n=1) and general practitioners (n=15) representing 13 general practices from across the four regions in England. There were fewer female participants (n=10, 45%) compared to males. Most participants were white (n=14, 64%). The number of years of practice varied widely among participants, from three to over 40 years.

Co-design workshop participants included six healthcare practitioners, consisting of two community pharmacists, three general practitioners and one practice nurse, three older people living with cancer and one commissioner of cancer services in the Eastern region of England. There was a balance of male and female participants, and the majority were white (n=7, 70%). There was representation across the four regions in England, with the majority from the Eastern region (n=7, 70%). Together with three members of the research team, eight to nine participants were present at each of the three co-design workshops. The same participants attended each of the workshops; however, one practitioner missed two workshops and a second practitioner and the commissioner missed one workshop, all due to other work commitments.

5.4.2 Empathise

Understanding the barriers to and enablers for delivering self-management support to older people after completion of anticancer treatment

Participants reported barriers at practitioner, patient, organisational and health system levels at the three discovery workshops. Table 16 summarises the barriers to delivering self-management support in community pharmacy and general practice, with illustrative quotes

from participants. Table 16 also shows the derived recommendations to address barriers, synthesised by the research team after the workshop.

Practitioners reported that some patients felt empowered to manage their own health and wellbeing and hence did not need additional support from the primary care team. But there were also patients who persevered on their own at home despite needing support after anticancer treatment. Participants suggested this may be due to patients not being able to recognise any 'warning signs' or not wanting to 'bother the doctor.' Participants described struggling to find the balance between empowering patients to seek help when they needed it and offering support when it may not be needed, participants referred to this as 'medicalising' care. Participants indicated that older patients who completed anticancer treatment were often 'invisible' to the primary care team. Practitioners therefore agreed that a mechanism to identify patients who would benefit from self-management support was needed. Moreover, practitioners acknowledged that as the support needs of people who completed initial anticancer treatment may change over time, a process for regular patient reviews was needed. Participants suggested that this process could be similar to that employed in general practices for the annual review of patients with other chronic conditions, such as asthma, heart failure and rheumatoid arthritis.

Participants described organisational and system level barriers that hampered communication across different care settings. Participants believed that communication between the hospital cancer care team and the primary care team could be improved if both teams were included in end-of-treatment meetings and if the timeliness, quality and content of letters provided by hospital cancer care teams to general practice teams were improved. Practitioners also reported facing competing priorities, such as tasks to meet the requirements of the NHS Quality and Outcomes Framework, a pay-for-performance contract for UK primary care. Practitioners added that there was provision in this framework for maintaining a register of patients with a cancer diagnosis, and for undertaking a one-off

Cancer Care Review with these patients within six months of a cancer diagnosis. A Cancer Care Review is a discussion between a patient and their general practitioner or practice nurse about their cancer journey. The discussions aim to understand the experiences and concerns of patients and inform patients of the local services available to meet their support needs. However, participants expressed challenges in completing Cancer Care Reviews with patients due to lack of resources, uncertainty of when they should be done and the review being perceived as a ‘tick box’ exercise.

Table 16: Participant insights into barriers to supporting self-management in primary care and recommendations and proposed practitioner tasks to address them

Selected practitioner quotes	Barriers to delivering self-management support by primary care teams	Recommendations to address the barriers	Proposed practitioner tasks to address barriers
Patient-level barriers: "I think a lot of the elderly may hang on for too long at home and not be able to necessarily access what they need to try and deal with symptoms and problems following cancer treatment." [DW3-Pt9-GP] "There wasn't really any reason for them to contact the surgery [general practice], you know the people I'm talking about, they didn't have any [thing] remarkable, they didn't have other medical conditions [or] have any need and weren't on any registers so we wouldn't have picked them up." [DW3-Pt7-GP] "I have a lot of patients who don't speak English. It's a very cosmopolitan area and sometimes providing support for them in the traditional way is sometimes challenging … they might not want to access us because they don't have the language skill and also sometimes when they access us … what they have been given is not what, um, they actually need but that is what is available." [DW2-Pt1-GP] "I've got a really good strong relationship with probably the majority of my regular patients in my pharmacy … those kind[s] of people [patients] probably [feel] a bit more um comfortable opening up to someone they trust." [DW1-Pt3-P] "we're quite a small practice … and we know a lot of our patients very well … I think having that sort of relationship is important sometimes for people to bring up the matters that, you know, that are important to them." [DW3-Pt9-GP] "Would having an 'annual proactive health check'	• Older patients with cancer may hesitate to seek assistance. • Older patients with cancer may become 'lost to the system'. • The support offered may not be suitable for all older patients with cancer. • Older patients with cancer may lack rapport with or trust in primary care teams.	• Primary care teams need to proactively engage older people in discussions about cancer and cancer treatment. • Primary care teams need to introduce a regular review of patients with a cancer diagnosis. • Primary care teams need to tailor support to meet the unique needs of the older patient with cancer. • Support needs to be provided in a setting that is familiar to the older patient with cancer.	Annual patient follow-up Provide tailored support or signpost to services suitable for meeting patient needs

help people to better self-care in between times-reminding them of the services out there-but also helping them know when we want to see them and are concerned." [DW3-Pt2-GP]				
Practitioner-level barriers: "My knowledge of cancer treatment is pretty small you know because it's not something we see on a day-to-day basis." [DW1-Pt3-P] "I was a bit naive to know … what other support I could get for the patients who had been through treatment and sort of how to help them access further support." [DW3-Pt4-GP] "If we're going to signpost people to help with self-management, where are we meant to be signposting those people to?" [DW2-Pt6-GP] "we've got to be careful that we don't look for work when it's not needed because that is detrimental to self-management, isn't it, medicalising things that people are managing themselves, really it's about getting that balance and letting patients know that we're here if they need to approach us." [DW2-Pt6-GP] "Being too proactive and having reviews and having to pull people [patients] in and not helping them really to facilitate self-care wouldn't always be a positive thing." [DW3-Pt4-GP]	• Primary care teams have limited knowledge of cancer treatments and their potential side effects. • Primary care teams lack awareness of local information and services available to support older patients with cancer. • Primary care teams are uncertain about whether to proactively promote self-management ('top-down' approach) or offer support reactively on the request of the older patient with cancer ('bottom-up' approach).	• Primary care teams need training to increase their knowledge of cancer treatment. • Primary care teams need to familiarise themselves with locally available information on self-management and cancer support services. • Primary care teams need to agree on the approach (proactive 'top-down' vs reactive 'bottom-up') to provide support to older patients with cancer.	Access local resources to facilitate delivery of self-management support	Provide tailored support or signpost to services suitable for meeting patient needs
Organisational and system-level barriers: "I mean with the best will in the world …I haven't got 30 to 45 minutes to sit down and you know as much as I want to support my patients you know a) I haven't got the skills to do that degree of counselling, b) I haven't got the time to do it." [DW3-Pt6-GP] "I agree that the communication [between primary and secondary care] needs to be better but	• Primary care teams have limited capacity and competing priorities which hampers delivery of self-management support to older patients with cancer. • There are no	• Primary care teams need to identify potential local resources (e.g., workforce, existing systems/processes) to support delivery of the service to older patients with cancer. • Primary care teams need	Access local resources to facilitate delivery of self-management support	

I think we need to figure out what is our role in that context and that may also be the case I think even more so for elderly people." [DW2-Pt5-GP] "Ideally we want to contact these patients more often but because of the pressure of work and having to compete with other priorities sometimes they might be lost in the system." [DW2-Pt1- GP] "We don't have a robust system in place for identifying these patients who have gone through that [cancer treatment]." [DW3-Pt7-GP] "Having lost medicines use review from our pharmacy contract we've lost opportunities to sit down and have this conversation with patients." [DW1-Pt1-P] "This patient has had cancer; the survivor is elderly. Right let's go through all of these patients … it becomes … tick box in nature." [DW2-Pt3-GP] "There is a QOF thing around a cancer care review which prompts you to review a patient within 6 months of diagnosis, um but sometimes it is difficult to know exactly where that patient is up to." [DW2-Pt5-GP]	processes in primary care to identify older patients who will benefit from support for cancer treatment-related problems. • There are limited opportunities in primary care to assess the needs of older patients after they complete cancer treatment.	to develop a process to identify older patients who will benefit from support for cancer-related issues. • Primary care teams need to identify opportunities to assess support needs of older patients after they complete cancer treatment.	Identify patients that will benefit from self-management support

DW=Discovery Workshop; GP=General Practitioner; P=Pharmacist; Pt=Participant; QOF=Quality and Outcomes Framework

5.4.3 Define

Agreeing which barriers to supporting self-management should be tackled and exploring what the service might look like

Co-design workshop 1:

Synthesising data from the three discovery workshops and the realist review identified four tasks central to supporting self-management by the primary care team. Figure 20 provides the visual representation of the four tasks presented to workshop participants. Primary care teams are not currently undertaking these four tasks in the routine care of older people discharged from specialist hospital cancer services. Table 16 shows how the data from the discovery workshops are linked to these tasks and proposed strategies for addressing the barriers to undertaking these tasks.

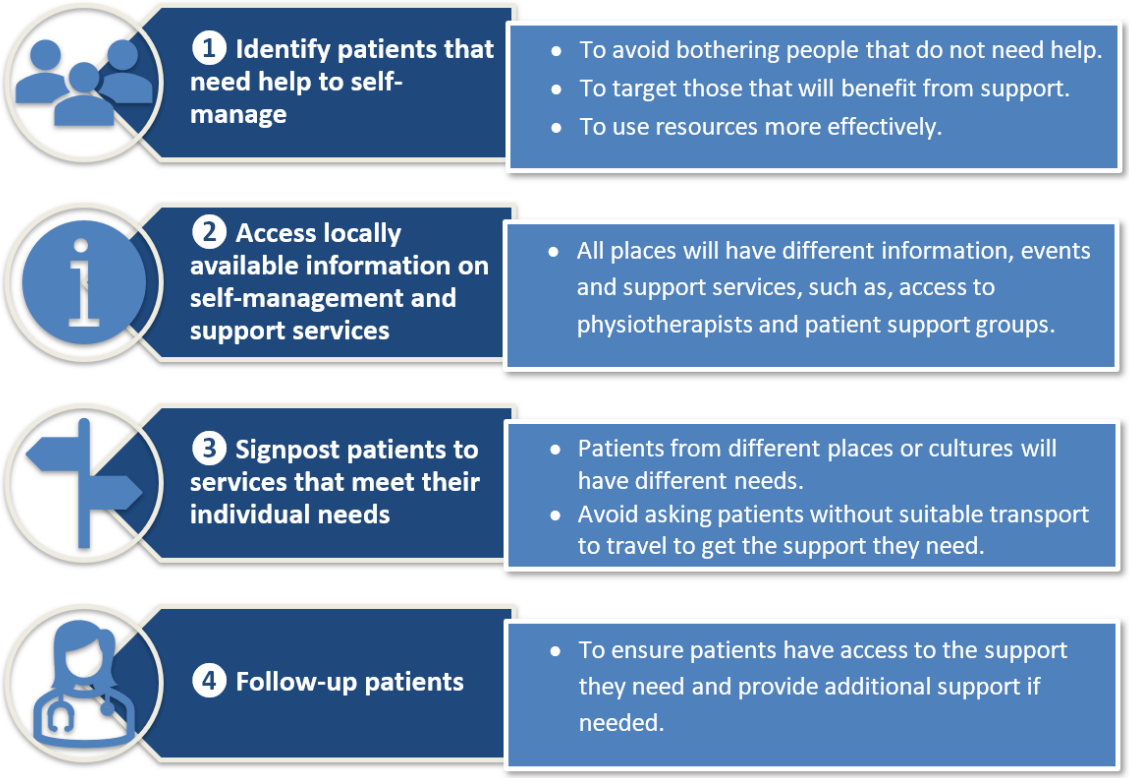

Figure 20: Practitioner tasks to support older people to self-manage long-term problems of anticancer treatment

Participants suggested that any member of the primary care team could be involved with supporting patients to self-manage. Support should be delivered from a location that is

familiar to patients and one that may be regularly visited. The team member offering patients support need not be the most senior practitioner, such as the pharmacist or general practitioner. Other members of the community pharmacy team, such as, pharmacy counter assistants, or general practice team, such as, practice nurses and receptionists, may be appropriate to offer support, provided they had the knowledge and skills to perform the tasks. Participants highlighted that many experienced practice receptionists and members of the administrative team were trained as 'care navigators'. The role of these care navigators was to actively listen to patients, provide information to help patients access the support they needed and to help them play an active role in managing their own health. Participants explained that it was important to have escalation processes in place to ensure patients could be referred to senior practitioners if necessary. Participants further highlighted that both resources and capacity in primary care were limited and therefore delivering a new service could be challenging.

Two of the three patient personas were used in the workshop to explore how and when patients may interact with the primary care team with respect to support to manage long-term anticancer treatment related problems. The insights gained from discussions using the personas are summarised here. Patients require support across multiple domains, including those beyond the direct physical consequences such as, emotional, practical and social support. Patients may be able to self-manage immediately after completing cancer treatment, but over time this may change. Unless practitioners maintain regular contact with patients, they are likely to become 'lost to the system.' Participants suggested this could be achieved through an annual review. Patients also need to feel empowered to seek out support, especially if they had numerous unmet needs. Practitioners need to use a holistic approach to gauge how much information or what support the patient requires. Practitioners need to tailor information or support based on the unique needs and ability of patients. Patients may not be able to sustain self-management over time, due to deterioration of physical or mental health and changes in social circumstances. Practitioners will therefore

need to periodically reinforce information about how patients can self-manage their health and wellbeing and when to seek help. Practitioners also need to be aware of the complex dynamics between patients and carers. Some patients may rely on carers to raise cancer treatment related concerns with practitioners, which carers may downplay or overstate.

Reflections, synthesis and planning: Developing potential service pathways to address barriers to delivering self-management support

After the first co-design workshop, the research team discussed the potential service pathways emerging from the activities and discussions, which informed the aims for the next workshop. Participants described two main approaches to identify patients who might benefit from self-management support: a structured ‘top-down’ approach or an opportunistic ‘bottom up’ approach.

The four potential service pathways developed from the co-design process are shown in figure 21. They all focused on how to identify patients who need help to self-manage, which was the key barrier to delivering support for self-management. Participants highlighted that there were primary care interventions to support patients and referral pathways to secondary care and signposting. But participants emphasised that there were no mechanisms to identify patients who needed support to self-manage.

The workshop discussions emphasised the importance of utilising different members of the primary care team for the different tasks which participants believed would address resource and capacity issues related to delivering a new service. Synthesis of workshop discussions therefore led to proposing that at least two members of the community pharmacy and general practice team could be involved. This would entail one member of the team who is usually the first point of contact with patients, e.g., general practice receptionist (care navigator) or pharmacy counter assistant, to identify patients requiring support to self-manage. They would refer patients to a second member of the team, who is appropriately

trained and skilled to assess patients' needs, e.g., practice nurse or pharmacist. After assessment, the second member of the team would signpost patients to local information or services tailored to meet their unique needs, e.g., peer support groups or social prescribers. The tasks undertaken by the two members of the team involved in the pathway would be those performed during routine care of patients. This approach addresses resource and capacity limitations in primary care, by using existing members of the team, with the relevant knowledge and skills and embedding self-management support in routine care.

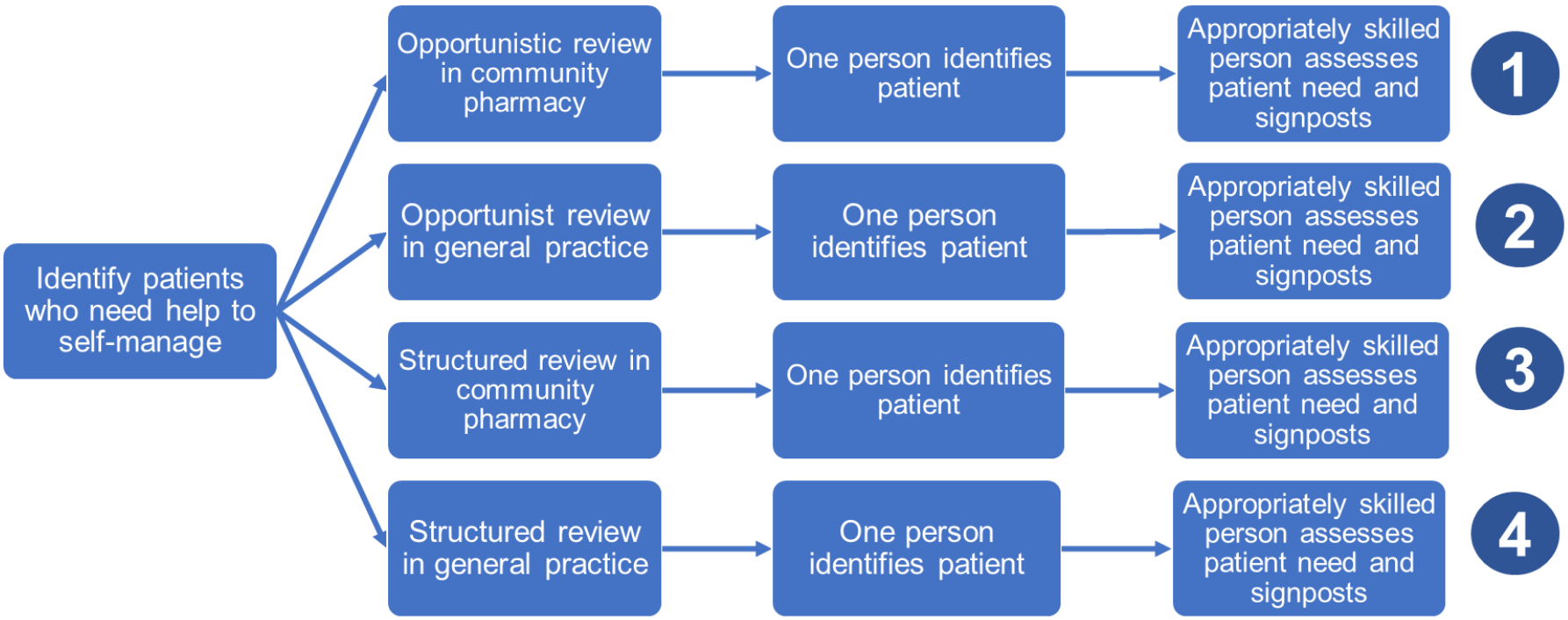

Figure 21: Potential service pathways to support self-management in older cancer survivors

5.4.4 Ideate

Iterative development of a promising self-management support service pathway

Co-design workshop 2:

This workshop aimed to establish: (1) the setting where the service will be delivered from, i.e., community pharmacy or general practice, (2) whether a structured or opportunistic approach should be taken, and (3) which team members were best placed to identify and signpost patients/offer support.

The four service pathways developed from co-design workshop 1 were first presented for discussion before the evaluation matrix was used to vote for and select which pathway, if any, would be taken forward. During the discussion it was clear that participants preferred a general practice delivered model that included a structured review (see Table 17), but that community pharmacists could also have a role in raising awareness about the service and signposting patients.

The criteria for VALUE of the pathway to service users and providers and COMPLEXITY for delivering the pathway, developed by participants during the first activity of this workshop are shown in figure 22.

Participants unanimously voted that a structured review in general practice was likely to offer high value and be the least complex to set up and deliver. Co-design participants highlighted various methods for identifying patients who might benefit from additional support to self-manage, including, identifying patients by the wider practice team, a triage system/tool to identify patients with unmet support needs and displaying posters to raise awareness of how patients could seek out local support for cancer treatment related problems, if needed.

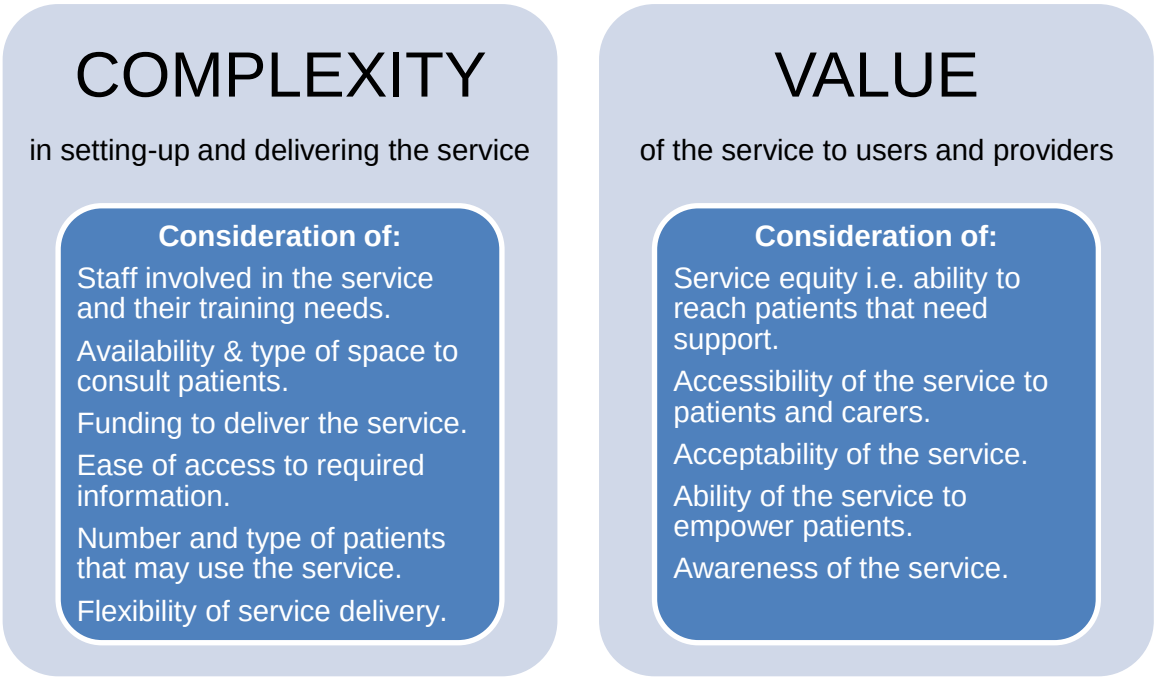

Figure 22: Criteria to evaluate value and complexity of the service pathway

Table 17 shows the synthesis by the research team of the key concepts for the four potential service pathways and the transition to the proposed service pathway, including the rationale for changes. Figure 23 provides the diagrammatic representation of the four main components of the proposed service pathway, developed from the workshop discussions, that was presented to participants at the final co-design workshop.

Table 17: Iterative co-design of a service pathway to facilitate self-management support by primary care teams to older patients with cancer

Key concepts for potential service pathways	Recommended changes to potential service pathways	Rationale for changes	Proposed service pathway
1. Opportunistic review vs structured review	• Participants emphasised the need for a *structured review.* • The review should be done on an annual basis. • In addition, patients could be reviewed opportunistically, if needed.	• Structured reviews will reduce health inequity and ensure no patient is 'lost to the system.' • Structured reviews enable intervention capture or 'coding' to facilitate remuneration. • Regular reviews ensure that the primary care team can respond to changing needs of patients.	The annual structured review in general practice will include the following main components: • Practice team sends out a brief survey for patients to complete • Practice team review patient survey to identify support needs • Practice team follow-up patients who need support • Practice team contact patients who do not complete brief survey
2. Service delivery in community pharmacy vs general practice	• The structured review should be provided in *general practice*. • Community pharmacy teams could be involved with raising awareness of the service in general practice.	• Practices have a register of patients diagnosed with cancer, which can be used to identify older patients with support needs after they complete cancer treatment. • Practices already have referral pathways in place. • Training, if needed, may be easier to deliver in general practice. • Setting up and delivering the service in pharmacies will be challenging given the lack of access to patient records, referral pathways and electronic systems.	
3. Involvement of multiple members of the primary care team. One member of the team identifies patients requiring support and makes a referral to another member of the team, with appropriate knowledge and skills, to assess patient needs and	• A semi-structured tool should be used to assess patient needs ○ The tool must be designed to allow administration via multiple modes, e.g., paper, online, telephone, etc.	• A semi-structured tool would ensure all potential support needs are identified – physical, emotional, practical and social. • Multiple modes of administration will ensure patient preferences are considered. • Involvement of wider team members would ensure service	

offer support/signpost to local information or services, that meets the patient's individual needs.	• Multiple members of the team could be involved in identifying and supporting patients, provided all have the relevant experience. • There needs to be a way to identify those patients that did not respond to the initial contact.	continuity and workforce development. • Using existing teams, with the relevant experience, to deliver the service addresses potential resource limitations. • Systems to identify patients who did not respond to the initial contact will ensure that patients with support needs are not missed.	

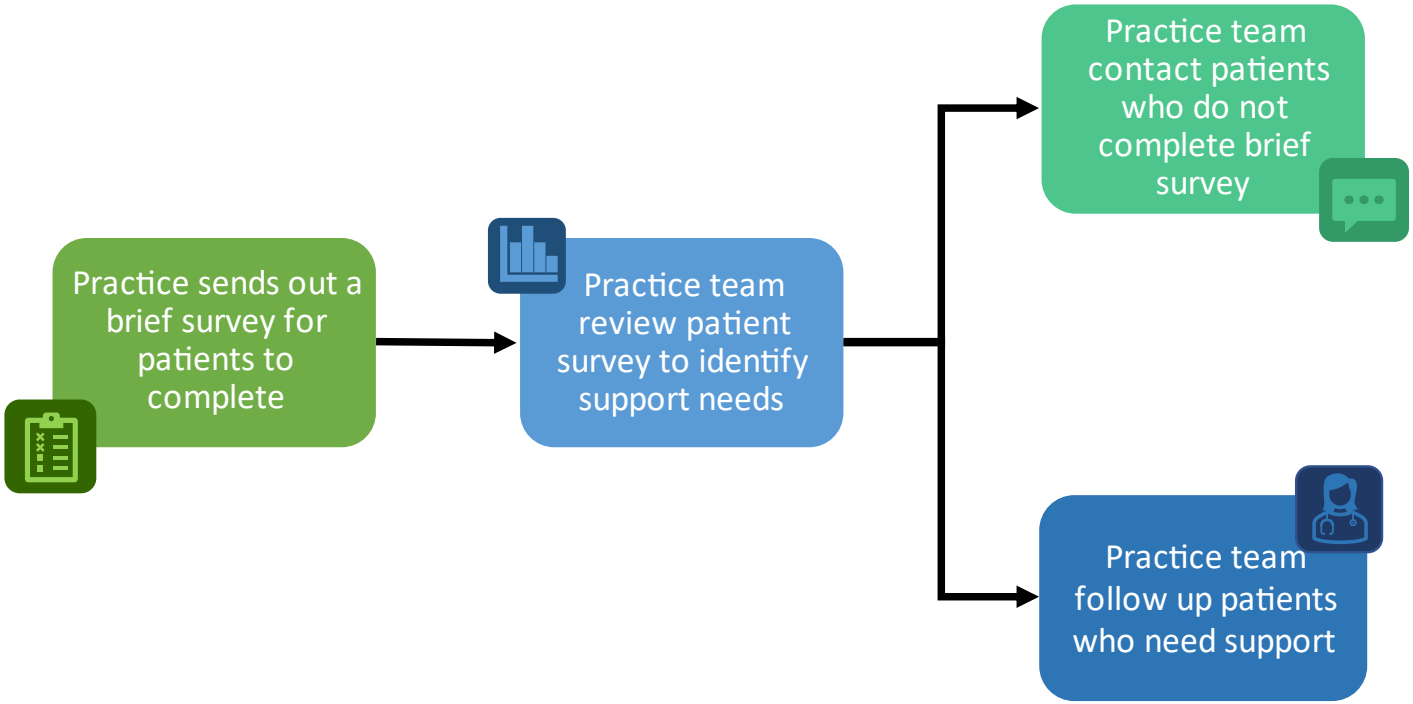

Figure 23: Refined co-designed service pathway to support self-management in older cancer survivors

Co-design workshop 3:

The service pathway shown in Figure 23 was presented to participants for discussion and refinement. Participants emphasised that a senior person in the practice would need to take ownership and responsibility for the new service to get 'buy-in' from all members of the practice team. They also suggested that patients could be identified through existing patient lists, e.g., the register of cancer patients kept as part of the cancer indicators for the Quality and Outcomes Framework, by one member of the practice team, with sufficient level of experience, who could refer patients to another appropriate member of the practice/wider primary care team.

The brief survey would need to be offered in various formats to ensure ease of patient access and each practice could decide on the timing for administering the survey. Participants suggested that the survey questions could include different domains, such as physical, emotional, social, and practical needs, which are linked to practice team members that can offer support. For example, if a patient was identified as needing help with social activities, then the member of the practice team reviewing survey responses, could refer them to a social prescriber linked to the practice. For patients who did not complete the brief survey, participants suggested various options for recalling the patient e.g., phoning patients, electronic alerts using existing communication processes/systems or reminding patients to complete the survey when they came in for routine appointments to the practice. Several participants emphasised the importance of having an initial question about whether the patient had any needs – Yes / No – so that patients with no needs would not have to complete the whole survey and the practice would know.

Co-design participants were supportive of the community pharmacy team being involved with the refined pathway and made various suggestions of how this could occur. The pathway could be advertised via established professional networks to raise awareness of the service, practices could be made aware of services within community pharmacy that patients

could be referred to e.g., smoking cessation clinics, and pharmacy teams engaging patients in discussions about local practice initiatives to support patients once they complete anticancer treatment. Participants emphasised that a service specification would need to be in place in pharmacies to evaluate the role of pharmacies in the proposed service.

Participants were confident that support, care, treatment and services already exist and that the key barrier that the intervention addressed was identifying patients with needs for support and acting on this.

Reflections and synthesis:

Patient engagement with main components of a prioritised service pathway and involvement of the wider primary care team

The co-design approach successfully brought primary care teams, patients, commissioners, and the research team together to design an intervention to support people to self-manage the long-term problems after completing anticancer treatment. The intervention will be delivered in general practice and will involve a structured review of all patients with a cancer diagnosis to identify those who might benefit from additional support. The intervention will employ similar processes used in general practices for the annual review of patients with other chronic conditions, such as asthma and rheumatoid arthritis. It was clear that the wider primary care team will play a role in raising awareness of the service in general practice and potentially be involved in supporting patients, e.g., pharmacy teams would be central to supporting patients with medicines related issues.

Some questions remain unanswered, however. It is unclear which members of the practice team will be involved in the main components of the intervention. Practice teams will likely need training to support them in the delivery of the pathway, but what this training will look like and who will deliver the training needs further exploration with key stakeholders. It may be possible to automate some components of the intervention. The questions in the brief

survey, the domains to target, and who and how referrals will be made need further consideration and will be pivotal to the success of the proposed service. Some participants suggested that all patients should have an annual review of their support needs for self-management. However, this will need balancing against the available resources and the evidence suggesting that only half of older cancer survivors need support for self-management.

5.4.5 Linking the workshop findings to the realist review

The realist review in Chapter 4 identified five enablers to guide development of an intervention to facilitate practitioners to provide self-management support. The discovery workshop participants agreed that these were appropriate to address the perceived barriers to delivering self-management support in primary care. The realist review extracted determinants in the context of enablers whilst in the discovery workshop participants articulated determinants as barriers. In all cases the enabler identified from the realist review addressed the barriers identified in the discovery workshops. Table 18 provides a summary of the identified enablers and associated TDF domains with linked BCTs identified from the realist review. Table 18 also includes the key insights gleaned during the workshops to facilitate the intervention development and selection of the BCTs to address identified barriers. How the components of the prioritised service pathway link with the five realist programme theory and existing practice resources are shown in figure 24.

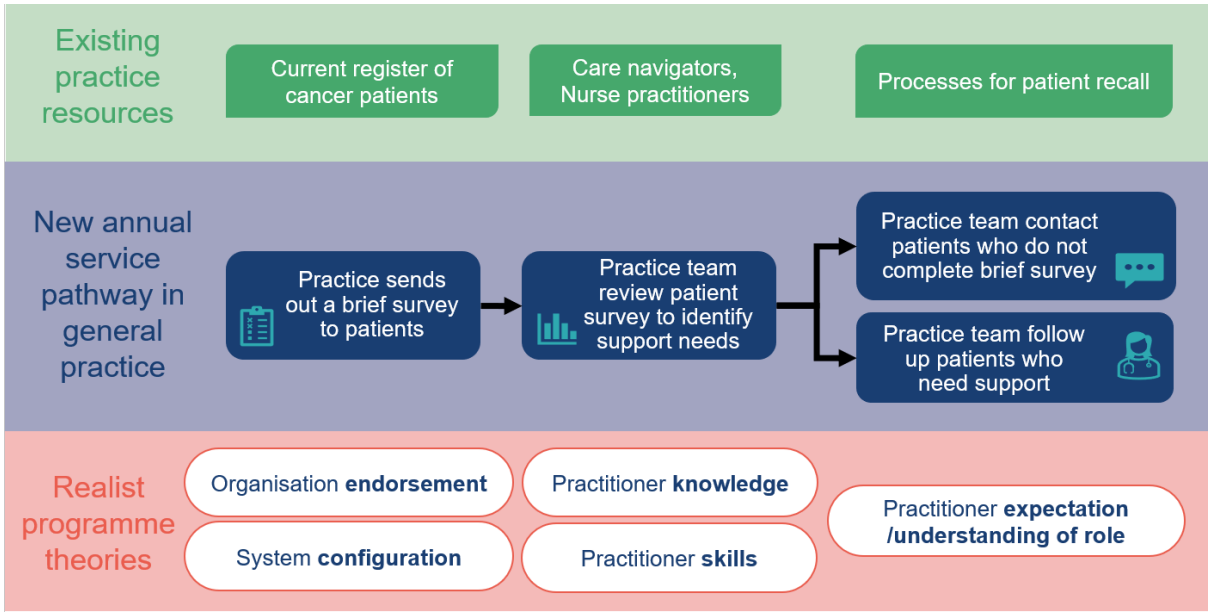

Figure 24: Prioritised service pathway (blue) showing links to the realist programme theories (orange) and existing resources (green) to deliver self-management support by general practice teams

Table 18: Enablers for delivering self-management support, associated domains of the TDF, linked BCTs and BCTs delivered by the co-designed service pathway in general practice

		Realist review (Chapter 4)		Co-design workshops (Present Chapter 5)	
Enabler	**TDF domain**	**BCTs linked with the TDF domain identified from the TATT**	**BCTs identified in the realist review (Yes/No)**	**Insights to support intervention development**	**BCTs delivered by intervention**
Practitioner knowledge	Knowledge	Feedback on behaviour	Yes	Existing general practice teams have the required knowledge to deliver the intervention. Behaviour not required for intervention delivery.	Not applicable
		Biofeedback	No		
		Instructions on how to perform behaviour	Yes		
		Information about antecedents	Yes		
		Information about health consequences	Yes		
		Information about social & environmental consequences	Yes		
Practitioner skills	Skills	Problem solving	No	Existing general practice teams have the required skills to deliver the intervention. Behaviour not required for intervention delivery.	Not applicable
		Instruction on how to perform behaviour	No		
		Demonstration of the behaviour	Yes		
		Behavioural practice/rehearsal	No		
		Generalisation of target behaviour	Yes		
		Graded tasks	No		
		Self-reward	No		
Practitioner and patient understanding of their roles & responsibilities	Social/ professional role & identity	Social support (unspecified)	Yes	Intervention embedded in general practice to align with Quality Outcomes Framework requirements	Social comparison
		Social comparison	Yes		
		Credible source	Yes		
		Identity associated with changed behaviour	No		
Organisational	Intention	Goal setting (behaviour)	Yes	Intervention embedded in	Incentive

prioritisation of self-management support				general practice to align with Quality Outcomes Framework requirements.	(outcome)
		Commitment	No		
		Information about health consequences	No		
		Information about others' approval	Yes		
		Incentive (outcome)	Yes		
		Valued self-identity	No		
Health system configuration to integrate self-management support in routine care	Environmental context & resources	Problem solving	Yes	Intervention incorporates the use of a survey to identify patient support needs	Restructuring the physical environment
		Social support (practical)	Yes		
		Prompts/cues	Yes		
		Remove aversive stimulus	No		
		Conserving mental resources	Yes		
		Restructuring the physical environment	Yes		
		Restructuring the social environment	Yes		
		Avoidance /reducing exposure to cues for the behaviour	No		
		Adding objects to the environment	Yes		

BCTs Behaviour Change Techniques; TDF Theoretical Domains Framework; TATT Theory and Techniques Tool

5.5 Discussion

This study sought to learn from the expertise of primary care teams, patients and commissioners to collaboratively develop an intervention to support older people to self-manage long-term problems caused by anticancer treatment. Design thinking was employed to leverage insights from key stakeholders to co-design an intervention that was acceptable and feasible to primary care teams and patients. Co-design enabled identification of the four tasks that primary care teams should undertake to support older cancer survivors to self-manage and for these to be configured into one service pathway.

The prioritised co-designed pathway resembles current pathways in general practice for the annual review of patients with long-term conditions, such as, asthma or dementia. Practices in England already maintain a register of patients with a cancer diagnosis. The pathway is designed to identify patients from this register that have completed anticancer treatment and who will benefit from self-management support. This structured, proactive approach ensures that all patients with a cancer diagnosis registered with the practice are offered support, should they need it. Older patients with cancer may hesitate to seek out information or assistance from primary care teams on their own, as they may want to maintain their independence, normalise problems as being part of the ageing process or believe that it is not appropriate to seek assistance for perceived minor problems [231, 232]. Relying on older patients to seek out help to self-manage may therefore be inappropriate, as they may not be willing or able to access or engage with practice teams [73]. This is often true in patients living with multiple conditions and those that are socio-economically disadvantaged [233]. The principles of the inverse care law [234], highlight the pervading inequity in healthcare. Applied to the present study, this suggests that people needing the most support for self-management from healthcare teams are the least likely to receive it. This was reflected in workshop participants voicing their experiences of some older cancer survivors not being able to access information and resources in the same way as their younger counterparts and

not having sufficient health literacy to enable understanding of the information and support and apply it to their everyday lives. Interventions reliant on patients seeking out support for self-management may therefore perpetuate inequity, whereas the intervention in the present study is designed to remove care disparities by assessing all patients to determine their self-management support needs.

The final co-designed pathway incorporated findings from the present study and the realist review, described in Chapter 4. The enablers facilitating practitioners to deliver self-management support identified in the realist review did not correspond well to those identified in the current co-design study, with respect to practitioner knowledge and skills. The realist review found that practitioners needed to be equipped with appropriate knowledge about the consequences of cancer treatment and cancer care pathways and consultation skills to engage cancer survivors in discussions about self-management. But in the present study, participants highlighted that existing general practice staff already have the necessary knowledge and skills to support self-management among cancer survivors. This divergence may be due to the realist review findings being drawn from multiple healthcare settings, whereas the present co-design study was specific to the NHS general practice setting.

The key difference between current pathways in general practice and the pathway proposed in the present study is the use of a brief survey to identify patients from the register who will need help to self-manage. Co-design participants felt that this was an important step to ensure that patients who felt able to self-manage without further input from the practice team could continue to do so, whilst those patients who needed help were identified and support tailored to their needs. This would ensure appropriate use of the limited resources within practices. This may be important for sustainability of the proposed pathway in general practice where demands for services are high and capacity is limited. The proposed pathway is designed to be flexible, which could allow busy practices to adapt components to meet the

needs and priorities of the practice and involve wider members of the primary care team, such as pharmacists, or social care teams.

Funding and training for primary care teams will be key factors for implementation and sustainability of the proposed pathway. Funding may be addressed by linking to policies or local health priorities. In England, Primary Care Networks [235], which are local partnerships between general practices and community, mental health, social care, pharmacy, hospital and voluntary services, could fund the proposed pathway to enable proactive, personalised and more integrated health and social care for older people living with cancer. The proposed pathway could also facilitate delivering the Cancer Care Review, part of the Quality Outcomes Framework for general practices in England. The updated Quality and Outcomes Framework 2021/22 guidance, which was published after completing the present study [236], requires general practice teams to undertake a Cancer Care Review within 12 months (previously 6 months) of a cancer diagnosis, using a structured template. Additionally, general practice teams need to discuss with patients the support available from primary care within three months of a cancer diagnosis. The intervention developed in the present study could facilitate delivery of the Quality and Outcomes Framework indicators for cancer, as we have embedded the use of a survey to determine patient support needs and signposting to local primary care services.

The proposed pathway may need further refinement. Time and resource restrictions prevented development and testing of a ‘prototype’ pathway. Recruitment methods within the time constraints of the PhD led to patient representative participants from a similar background – white, educated and all with a history of solid cancers. However, voice to patients from minority and disadvantaged socioeconomic backgrounds was given by using patient personas. In addition, some practitioners involved in the co-design workshops were from minority backgrounds or cared for patients with socially deprived backgrounds and were thus able to articulate specific needs of these populations. Future pathway

developmental work should, however, include patients from heterogenous backgrounds, and with both solid and haematological cancers. Only one nurse participated in the co-design workshops, with limited experience of supporting older patients with cancer. This likely represents the scope of practice of most nurses in primary care. The most common areas of clinical practice for nurses in general practice are management of long-term conditions, immunisation and health promotion [237]. Future pathway development work should ensure that there is more representation from nurses, allied health professionals and social care teams to ensure perspectives of all service providers are considered. Finally, the co-design workshops were done online due to COVID-19 related restrictions, which limited the use of physical objects, such as LEGO® Serious Play® and Thinking hats [238], which are popular for in-person co-design workshops. The visual aids and workshop activities were therefore adapted for online discussions, such as encouraging the use of video so that participants could see each other, research team sharing their screen with participants to communicate findings from earlier workshops, using the 'chat' function to complement verbal discussions or encourage new lines of thought, and using online polling and breakout rooms to simulate a face-to-face experience.

5.6 Chapter summary

The co-design approach engaged with key stakeholders to lay the foundations for a solution to address how general practice and the wider primary care team could deliver self-management support to older people living with long-term problems related to anticancer treatment. The proposed pathway enhances existing resources of locally available support and signposting patients, by adding processes to identify patients with unmet needs who do not access help and following them up to ensure unmet needs are addressed. This proposed pathway is flexible and aligns with the current general practice structures and processes, whilst facilitating involvement of the wider primary care team, such as, pharmacy teams.

Further engagement with providers and users of the proposed service is needed to refine, test and evaluate the pathway.

This chapter contributes to developing the logic model by identifying the four tasks that practitioners need to undertake to support self-management thus defining the behaviour that is required and then selecting the BCTs to address the determinants for this behaviour. Figure 25 shows the contribution of this chapter to the logic model.

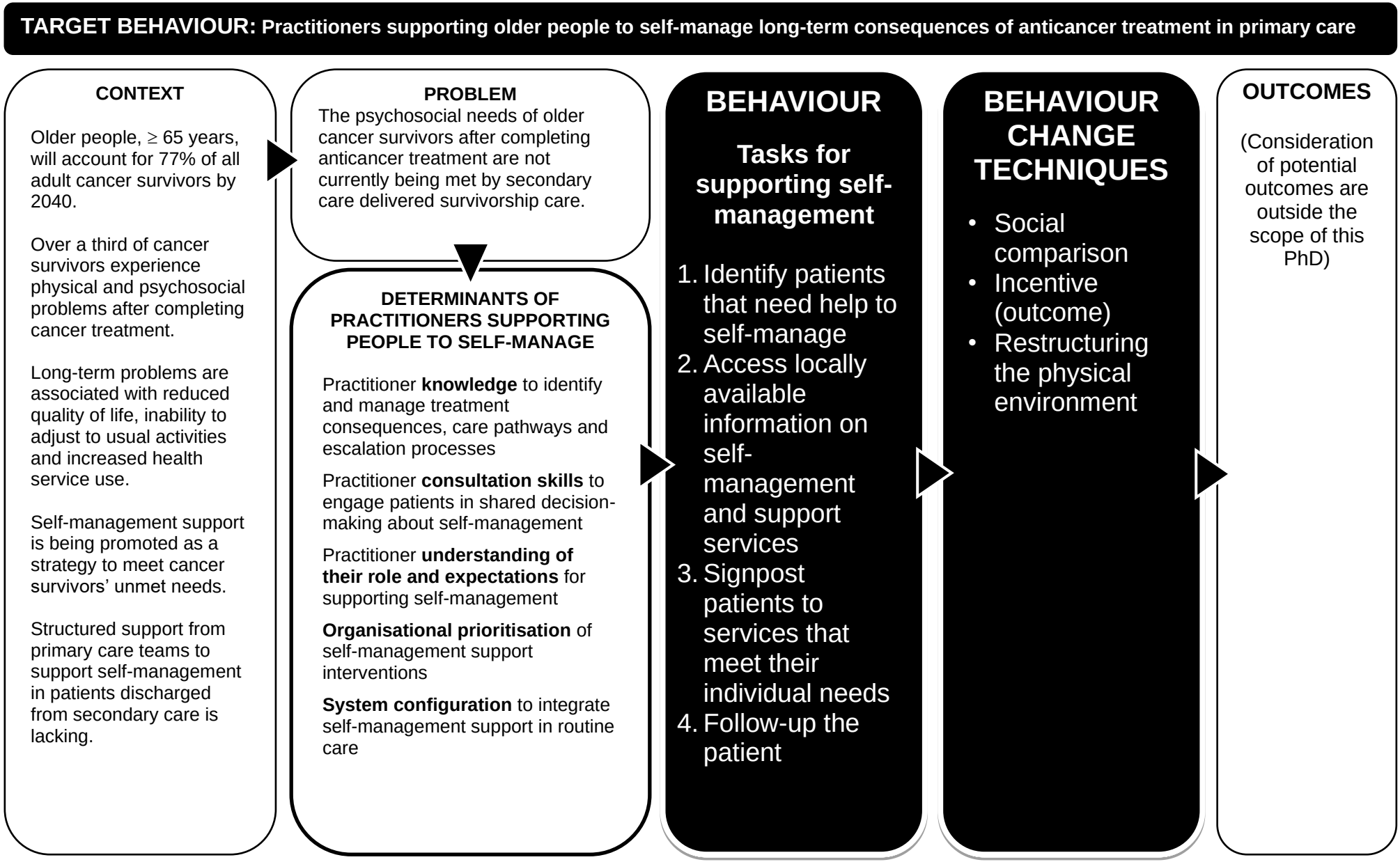

Figure 25: Logic model: contribution of the co-design study to identify practitioner behaviours and associated behaviour change techniques during intervention development

This co-design study contributes to the evidence base related to self-management support in adult cancer survivors, as summarised below:

Building on the evidence for self-management support interventions for cancer survivors:

- The intervention was developed specifically for older adults, who are the most rapidly growing population of patients with cancer. Although designed for older cancer survivors, the intervention may have applicability in any adult cancer survivor living with long-term consequences of anticancer treatment, which was also highlighted by the co-design participants.
- The co-designed intervention targets practitioners, rather than patients, to provide personalised self-management support. This approach strives to reduce inequity in cancer care by proactively identifying people who would benefit from additional support to self-manage.
- The intervention was designed for delivery in primary care and has the potential to utilise the full breath of clinical and non-clinical teams across health and social care. Further, it builds on the strength of primary care being the first point of contact for the majority of patients.

Methodological advancement

- This co-design study integrated explanations derived from a realist approach, combined with the TDF, to develop a theory-driven intervention incorporating the perspectives of older cancer survivors, primary care teams and cancer commissioners.

Chapter 6 Discussion

6.1 Introduction

This chapter synthesises the findings presented in this thesis. The overall aim of the research, as stated in section 1.7, was to design an intervention, targeted at primary care practitioners, to deliver self-management support to older cancer survivors living with long-term consequences of anticancer treatment. Chapter 1 set the scene for the research by providing a background for the study within the cancer survivorship care setting and introduced self-management support as an approach to empower cancer survivors to play a proactive role in their health and wellbeing. Chapter 2 provided a rationale for the methodological approach and underpinning theory used in this thesis. The scope and size of the unmet needs of older cancer survivors after completing anticancer treatment was investigated in Chapter 3, together with the perceived gaps in secondary care service provision. Following this, Chapter 4 reported on the five programme theories generated from the realist review to understand what works, for whom, why, how, and in what contexts in relation to facilitating healthcare practitioners to provide self-management support to cancer survivors. Chapter 5 moved on to present the co-design study, which consisted of discovery workshops and co-design workshops. The discovery workshops helped to refine the five programme theories generated in Chapter 4 to elucidate the determinants of practitioners supporting cancer survivors to self-manage in the context of the NHS primary care. The co-design workshops then established that the general practice team is best placed to lead self-management support and how the determinants of this behaviour may be addressed within existing resources and infrastructure. This chapter will summarise the key findings from the overall work presented in this thesis, along with strengths and limitations. Recommendations for clinical practice, research and policy arising from this research will then be summarised. The chapter will end with reflections of my overall PhD journey, undertaking realist research and conducting a co-design study during the COVID-19 pandemic.

6.2 Key findings

6.2.1 Scope and size of ongoing problems faced by older cancer survivors after completing anticancer treatment

One of the key objectives of this thesis was to estimate the prevalence of long-term side effects in older adults after completing anticancer treatment, and its perceived impact on overall health and wellbeing. Previous literature examining the impact of anticancer treatment in cancer survivors has included all adults [239] or focused on experiences of older adults during anticancer treatment [240]. Despite older adults accounting for a large proportion of cancer survivors, and the projected growth of this population, research about the experiences of older cancer survivors after completing anticancer treatment is limited. This thesis sought to narrow the gap in the evidence by examining the scope and prevalence of side effects in older adults after completing anticancer treatment, reported in Chapter 3. The cross-sectional study in Chapter 3 highlighted that 50% of older adults experienced side effects after completing anticancer treatment which negatively impacted their physical health, psychological wellbeing and social wellbeing. This is higher than findings reported by a cancer charity in the UK, of up to 25% of adults experiencing negative consequences after completing anticancer treatment [241]. The findings from Chapter 3 builds on the emerging literature and reinforces the evidence indicating that older adults are at a higher risk of developing side effects from anticancer treatment [11]. The cross-sectional study in Chapter 3 further inferred that side effects may continue to negatively impact the overall health and wellbeing of older cancer survivors beyond two years of completing anticancer treatment.

The study reported in Chapter 3 highlighted that side effects of anticancer treatment impacted the ability to manage other long-term conditions in about a third of older cancer survivors, with less than half feeling supported by healthcare practitioners to manage other long-term conditions. This finding builds on the literature highlighting the complexity of care

in older cancer survivors, given the high prevalence of other long-term conditions in this population [9].

Chapter 3 further highlighted that whilst a significant proportion of older adults experience long-term problems after completing anticancer treatment, they are polarised in their ability to self-manage these problems. Half of older people are effectively using existing NHS and social care resources to self-manage whilst the remainder have unmet needs. These unmet needs are most pronounced for the psychosocial consequences. This was supported by findings from both the realist review in Chapter 4 and the discovery workshops in Chapter 5, which identified that healthcare practitioners were reluctant to initiate discussions related to psychosocial concerns due to lack of knowledge of the support available. The realist review in Chapter 4, also identified that practitioners needed appropriate communication skills to initiate discussions about self-management with patients. Good communication skills include general interactional skills to convey empathy and support and to provide information that is understood and retained [242]. Both are essential for providing good psychosocial care in cancer survivors. The realist review in Chapter 4 identified that lack of interactional skills was a barrier to healthcare practitioners initiating discussions about self-management with cancer survivors.

6.2.2 Gaps in care to meet needs of older cancer survivors

Chapter 3 identified that during cancer treatment, the vast majority of older adults felt well supported by healthcare practitioners but this reduced to less than a third after completing treatment. The Chapter 4 realist review highlighted that healthcare practitioners not knowing their roles and responsibilities was a barrier to providing effective self-management support. This was endorsed in the Chapter 5 discovery workshops where pharmacists did not feel that self-management support was a part of their role. A qualitative study involving interviews with community pharmacists exploring their contribution to long-term condition management in England identified barriers to the provision of self-management support. The key barriers

to providing self-management support in community pharmacy were prioritising the dispensing role of pharmacists and lack of incentives for supporting self-management [243]. The same barriers were highlighted by community pharmacists in the discovery workshops reported in Chapter 5. Despite a willingness and belief that community pharmacists could contribute to supporting older cancer survivors to self-manage, the structure of the current NHS community pharmacy contractual framework was a key barrier.

The Chapter 5 discovery workshops also identified that whilst general practice teams recognised that they had a role in supporting self-management, they were hesitant to offer this support to older cancer survivors due to lack of information from the secondary care cancer teams regarding treatment and care plan and uncertainty about what was expected of them. A systematic review exploring the role of general practitioners in follow-up cancer care showed that better communication between specialist cancer centres and general practice would enable clearer allocation of roles [244].

Chapter 5 further revealed that a lack of a robust mechanism to identify the patients that would benefit from self-management support prevented healthcare practitioners from delivering support to older cancer survivors. It was recognised that not all patients may need or even want support to self-manage, so a process that would proactively enable identification of older people who would most gain from self-management support was crucial. This finding reinforced the Chapter 3 finding that half of older cancer survivors are effectively self-managing.

Gaps in cancer survivorship care are not unique to the UK. A recent review in the US found that despite considerable progress in cancer survivorship care, some cancer survivors were still “lost in transition” [245]. Many cancer survivors in the US are not receiving the care they need and find it challenging to navigate the health care system, and “continue to suffer with and die of the late and long-term effects of curative cancer treatments” [245]. The review

authors called for further policy initiatives and research to ensure that all cancer survivors receive quality, comprehensive and co-ordinated care.

6.2.3 Implications for cancer survivorship care in NHS primary care

There are persistent gaps in cancer survivorship care in the NHS after people complete cancer treatment, despite publication of the National Cancer Survivorship Initiative over 10 years ago [20]. Advances have been made in transforming cancer follow-up care in secondary care in the NHS in England, and are ongoing [246]. However, the biomedical model dominates thus care is focussed on identifying and treating illness, leading to slow progress in routinely providing person-centred care. There is a lack of research in supporting disadvantaged cancer survivor populations, e.g., older people and those from minority backgrounds. Older cancer survivors may have certain traits that influence their health seeking behaviour, such as not wanting to be a burden and accepting and adapting rather than questioning [240]. Older cancer survivors may further perceive problems as the normal ageing process and therefore not seek help. There has also been limited focus on developing services in primary care to support the long-term care needs of cancer survivors after treatment completion.

For the 50% of older survivors experiencing long-term problems after completing anticancer treatment, identified in Chapter 3, primary care teams may be ideally placed to provide self-management support, due to their accessibility, knowledge of the patients' medical and social history, expertise in long-term condition management and role in providing holistic care. Once discharged from secondary care, cancer survivors will often initially contact their primary care teams when cancer related problems arise [68]. Primary care teams thus have an important role to play in supporting people to manage long-term and late effects of cancer and its treatment. Primary care teams provide patients with behavioural and lifestyle guidance and advise on self-management strategies for promoting general good health, which are essential elements of cancer survivorship care [247]. Primary care teams also

have links to services that can offer additional support, such as links to health and wellbeing clinics, rehabilitation and welfare benefits advice [248].

General practice in particular, offers existing enablers to facilitate healthcare practitioners to provide self-management support, such as appropriately trained and skilled staff, such as practice nurses and care navigators, and processes for delivering ongoing support to patients with long-term conditions. Practice nurses are routinely involved in assessing, treating, providing self-management support and following up patients with long-term conditions. Cancer survivors with long-term conditions will therefore likely be known to the general practice teams and practice nurses, in particular. Additionally, care navigators, often a non-clinical member of the practice team are increasingly being employed in general practices to help identify and signpost patients to available services [249]. Care navigation in cancer survivorship care has been reported to improve quality of life of cancer survivors, increase collaboration between survivors and healthcare practitioners and reduce barriers to care access and healthcare costs [250]. The Quality and Outcomes framework for general practices in England, includes incentives for providing care to people with cancer [236]. Some of the cancer indicators within the Quality and Outcomes Framework were updated in April 2021 in recognition of the key role of general practice in supporting patients after cancer treatment. The main aim for amending the cancer indicators was to increase personalisation and timing of cancer care [236].

General practice teams have long-standing relationships with their patients and therefore may play an important role in providing person-centred care and addressing any health inequity. This could be achieved through providing structured proactive care tailored to the needs of individuals and recall systems to ensure ongoing monitoring of needs and access to appropriate services.

The self-management support intervention proposed in this thesis closely resembles existing pathways for cancer and other chronic diseases. The intervention co-developed in Chapter 5 evolved organically and is similar to the *Recovery Package* [251], which is a person-centred, proactive approach to support people living with cancer and aims to promote recovery after cancer treatment. The *Recovery Package* consists of four elements: personalised care planning based on a holistic needs assessment, information and support to maintain wellbeing, an end-of-treatment summary and a primary care review. Secondary care cancer care teams are responsible for the delivery of most elements of the R*ecovery Package*. Elements of the *Recovery Package* could be adopted or adapted by primary care teams. For example, the holistic needs assessment is a simple questionnaire completed by people living with cancer and assesses physical, practical, emotional, spiritual and social needs. This holistic needs assessment could be used to inform the survey questions which is part of the intervention developed in Chapter 5. Furthermore, signposting to local information and support services which are part of the intervention developed in this PhD, could complement the health and wellbeing information and support element of the R*ecovery Package*. Finally, the cancer care review which is part of the *Recovery Package* could be incorporated into the intervention proposed in this PhD, which includes offering people living with and beyond cancer information and support based on their self-reported needs via the survey. This support could also be informed by the end-of-treatment summary which is an element of the *Recovery Package*. The intervention proposed in this PhD could thus be an extension of the *Recovery Package*, where primary care teams are responsible for on-going support to cancer survivors who are no longer on secondary care led follow-up pathways. In addition, although the intervention proposed in Chapter 5 was designed specifically for older cancer survivors, it could be delivered to any adult cancer survivor because of the generic nature of the intervention. To evaluate the specific needs of older people, existing alternative approaches may complement the intervention developed in this PhD, such as, comprehensive geriatric assessments [252] or the electronic frailty index [253], commonly used in primary care.

The self-management support intervention proposed in this thesis may hold promise to address inequity in cancer survivorship care in the UK by narrowing the gaps identified in care provision for older cancer survivors. The intervention proposed in this thesis seeks to minimise care inequity by ensuring that older cancer survivors most likely to benefit from self-management support are proactively identified and that support is tailored to their needs, with a mechanism for following up patients regularly.

The intervention designed in Chapter 5 is underpinned by theory and addressed the determinants identified in the Chapter 4 realist review that are relevant to the NHS context. Chapter 5 also described progression from identifying barriers to selecting behaviour change techniques, which are shown in Figure 25. The intervention addresses barriers of practitioners not understanding their role and responsibilities related to delivering self-management support, lack of organisational prioritisation for self-management support and lack of structures in health systems to integrate self-management support in routine care. These are addressed by three behaviour change techniques – social comparison, incentive (outcome) and restructuring the physical environment. The logic model shown in Figure 25, however, does not show the link between practitioner tasks and intervention components. The logic model was therefore refined to show these links and is illustrated in Figure 26. The refined logic model now includes mechanisms of action rather than behaviour change techniques. Mechanisms of action, which are linked to the TDF domains, are characteristics of individuals and the social and physical environment which influence behaviour. An understanding of mechanism of actions is important to help selection of behaviour change techniques [228, 229]. Mechanisms of action also help in understanding the processes through which behaviour change techniques have their effects. The refined logic model shows the links between the practitioner tasks, determinants, mechanisms of action and intervention components.

6.3 Strengths and limitations

The strengths and limitations associated with the three empirical studies are discussed within the respective chapters (Chapters 3-5). The strengths and limitations related to the overall work presented in this thesis are discussed below.

A key strength of the research presented in this thesis is advancing the evidence for older cancer survivors. Whilst the evidence for the experiences, supportive care needs and how best to address needs has increased rapidly over the last decade for adult cancer survivors, the progress made for older cancer survivors has been slower. Studies done in younger adults may not be generalisable to older cancer survivors, due to complexities associated with the ageing process and higher prevalence of co-existing health conditions, such as heart problems, diabetes and arthritis, alongside cancer [254]. The lack of evidence-based research in older cancer survivors may have resulted in the delivery of sub-optimal care in this population [254]. The evidence generated in Chapter 3 of this thesis adds to the literature related to the impact of anticancer treatment in older cancer survivors. In particular, the unmet psychosocial needs of older cancer survivors after completing anticancer treatment. This finding influenced the development of an intervention in Chapter 5 to address this need.

The cross-sectional study design used in Chapter 3 was appropriate for estimating the prevalence of anticancer treatment-related side effects in older cancer survivors. A sample size calculation was done to determine the number of participants needed to provide a 95% confidence interval with a 4.9% margin of error. The study recruited to just over the required 300 participants, showing that the results were credible. To ensure recruitment targets were met, recruitment was extended to multiple sites in England; and achieved a high response rate of 88%. The sample included patients with breast, prostate and colorectal cancers, which are common and have high survival rates in older people, thus enhancing

representation of findings to the general older cancer survivor population in England. The study findings could be applied to other countries with a similar demographic and that have publicly funded healthcare systems, such as Canada and Australia [1, 22].

The review of the evidence undertaken in Chapter 4 used a systematic realist approach to synthesis the evidence. Multiple sources of evidence were used to strengthen understanding of what makes some self-management support interventions work and others not. Self-management interventions are complex. The effectiveness of self-management support interventions depends on local environments, resources and the beliefs and values of both cancer survivors and healthcare practitioners. Realist approaches accept this complexity, are iterative, involve stakeholders and draw on multiple evidence sources. This approach allowed a deeper understanding of the contexts and the underlying mechanisms involved in facilitating healthcare practitioners to provide self-management support. Application of a behavioural framework to the realist review further strengthened the understanding of not only the key elements needed for effective interventions but also the relationship between the elements.

Combining guidance published by the MRC in 2008 [88] with guidance published in 2019 on complex healthcare intervention development [89] ensured that the most up-to-date advancements in intervention development were applied when designing the intervention in this thesis. This involved simultaneously using multiple approaches such as engaging stakeholders in discussions, informed by theory, during co-design. A recent ‘call to action’ advocated for more research to optimise self-management support interventions in ‘real-world’ cancer care [75]. The authors called for better use of theory to develop interventions, a need to understand the contextual influences on the delivery of self-management support and the need to synthesis evidence using high quality systematic reviews, meta-analyses and realist reviews to inform research that addresses identified gaps. The research

presented in this thesis has endeavoured to incorporate some of these principles in advancing the knowledge related to self-management support of older cancer survivors.

The findings of the realist review were discussed with participants of the discovery workshops, which triangulated to refine understanding of the delivery of self-management support in the context of primary care in the NHS. This increased understanding facilitated designing an intervention that was appropriate for the general practice setting in England.

Incorporating the evidence from the realist review during the co-design process was helpful in focusing the discovery workshop discussions to identify the barriers and enablers to practitioners facilitating self-management support in the NHS primary care context. This was important given the time limit for each workshop. Using the evidence from the realist review also facilitated incorporation of theory into the design of the intervention in a language that was accessible to stakeholders. Use of theory improves the likelihood of the intervention being effective and feasible [89].

Discussions among the stakeholders in the co-design workshops were based on experiences of older cancer survivors in the NHS, derived from the Chapter 3 cross-sectional study. In addition, discussions in the co-design workshops were also informed by experiences of healthcare practitioners involved in the discovery workshops. This enabled development of an intervention that will be relevant and useful to the needs of both healthcare practitioners and older cancer survivors.

Stakeholder involvement was sought for all three empirical studies. The questionnaire used in Chapter 3 was reviewed by cancer survivors, healthcare practitioners and representatives from two cancer charities, ensuring that items included were relevant to older cancer survivors. Consultation of stakeholders in the study reported in Chapter 4 was embedded in the methodology, ensuring inclusion of multiple perspectives during the programme theory

development and prioritisation processes. Chapter 5 described involvement of general practitioners, practice nurses, pharmacists, cancer services commissioners and older cancer survivors, in co-designing an intervention. A key contribution made by the stakeholders was to ensure that the intervention was designed so that it could be delivered as part of routine care. Stakeholders were pivotal in offering potential ideas of how to do this and in deciding the solution to take forward, based on their unique contexts.

While the recipients of the intervention developed in this thesis are healthcare practitioners, some elements of the intervention are patient-facing, such as the patient survey. It is therefore acknowledged that the ultimate recipient of the intervention is the patient. A limitation is the lack of involvement of patients from underserved or minority populations. The voices of informal carers, who are key to supporting older cancer survivors [255], are also absent. Efforts were made to invite participants from diverse backgrounds to the empirical studies reported in this thesis. However, the recruitment for the studies were limited by the geography. The Chapter 3 cross-sectional study mainly recruited participants from East of England, where non-white people account for less than 10% of the population [256]. In an effort to be inclusive, the stakeholders involved in the programme theory prioritisation in the Chapter 4 realist review were invited from groups in the East of England and South East London. The composition of the group in South East London was diverse, with people from different backgrounds. Across the groups involved in the programme theory prioritisation, only one informal carer was involved. The study in Chapter 5 recruited participants from across England and had a mix of participants from different cultural and ethnic backgrounds, although all patients were from the same background. No informal carers were involved in the design of the intervention. It is likely therefore that the intervention developed in this thesis in its current form may not be appropriate for cancer survivors from underserved or minority populations. The intervention may need refinement to ensure that the needs of these populations are addressed.

Another potential limitation of the research in this thesis relates to the necessity for conducting online co-design workshops, due to COVID-19 restrictions. Co-design has traditionally relied on face-to-face engagement with stakeholders. The Stanford Design Thinking process used to support co-design in this thesis was developed for in person engagement using physical objects to guide and inform the design process. Consideration was therefore needed for how to adapt the face-to-face process into an online process. Adaptations made for this thesis are outlined in section 6.5.3 – reflections on co-designing during COVID-19. Successful online co-design involved sharing of existing knowledge, being 'fully present' for the duration of the workshop and being able to facilitate and encourage engagement and collaboration. Several steps were taken to ensure that these basic principles were followed. This involved lots of pre-planning for identifying what to share with participants, identifying the key aims and objectives for each workshop, selecting appropriate online activities to meet the aims and objectives and dividing tasks among the three facilitators to ensure the workshop ran smoothly and the participant experience was optimised. Running six consecutive workshops allowed iterative co-design of the intervention, enabling tailoring and refinement and improvement in the workshop facilitation and processes. A key advantage of having online co-design workshops was the ability to extend recruitment across England, and therefore overcoming geographical barriers to facilitate greater diversity in representation. None of the research team had been involved in online co-design in the past so this was a 'live experiment.' What is not known is if the results produced during the online co-design approach would have been different had the workshops been conducted face-to-face. Furthermore, a very limited range of activities were used during workshops. Some of the features of the software used were not explored which may have been useful, such as use of the online "whiteboard." Some researchers have posted 'co-design' kits to participants in advance of the workshops to prepare participants [221]. However, this was not an option due to resource and time limitations of the PhD.

6.4 Recommendations for clinical practice, research and policy

Recommendations for practitioners, clinical practice, research and policy arising from the overall work presented in this thesis are discussed below.

6.4.1 Clinical practice

The NHS in England has promoted self-management to empower people living with chronic conditions, including cancer, to play a more active role in their health and wellbeing [8, 20, 257]. Various overall recommendations arise from this thesis for practitioners and clinical practice related to delivering self-management support to cancer survivors, which are described below:

Improve healthcare practitioner understanding of their role in supporting cancer survivors to self-manage

The degree to which practitioners believe that a behaviour is aligned to their professional role and identity will influence whether they will implement the behaviour. Arranging or providing support between teams could influence whether they deliver self-management support to cancer survivors. This could be achieved by practitioners working together towards a common goal, e.g., when implementing an intervention to treat sepsis in the NHS hospitals, cooperation between teams was important for making practitioners feel that they were supported in their roles and could ask each other for advice if they needed help [258].

Using guidelines produced by a credible source, such as, a recognised professional body may also emphasise the role of practitioners in delivering self-management support to cancer survivors, e.g., using evidence-based guidelines endorsed by the Canadian Association of Nurses in Oncology resulted in sustained use of the guidelines by nurses supporting patients to manage cancer treatment related symptoms [201].

Targeting practitioner behaviour through peer comparison and feeding back information on how individual practitioner's or practitioner teams compared to those of others may be effective in improving understanding of practitioner roles, e.g., a study describing a hospital medication deprescribing intervention found that practitioners observing peers was effective in drawing attention to practitioners successfully deprescribing [259].

Healthcare practitioners should encourage cancer survivors to become active partners in their own health and wellbeing

Healthcare practitioners need effective communication skills to engage cancer survivors in discussions about self-management. This could be achieved through training in person-centred approaches, e.g., motivational interviewing techniques [192]. Healthcare practitioners should be encouraged to discuss self-management with cancer survivors at every encounter. A collaborate approach should be taken to empower patients to self-manage where they can. Cancer survivors should be provided with information to help them recognise signs and symptoms that require healthcare practitioner input and those that can be managed on their own.

Healthcare practitioners should be aware of available local resources for signposting to cancer survivors

Healthcare professionals should identify locally available resources for supporting cancer survivors to self-manage. Resources could include information, support groups, local cancer charities or self-management programmes that offer training and skills development to cancer survivors. Healthcare practitioners could reach out to services offering support to enquire how their patients could access the services. Healthcare practitioners could keep a local repository with all the relevant information and update this as more information is made available. Healthcare practitioners should consider making this information available in different formats such as paper or online, to accommodate the needs and preferences of their patients. Consideration will need to be given to making the information available in

multiple languages and for those with poor or loss of vision, those that are hard of hearing or for those with other disabilities.

6.4.2 Research

Research recommendations arising from the three empirical studies were described in the relevant chapters (Chapter 3-5). The recommendations arising from the overall work presented in this thesis are included below.

Understanding the unmet needs of older cancer survivors after completing treatment

Chapter 3 described the cross-sectional study to determine the prevalence of the long-term consequences of anticancer treatment on older cancer survivors and satisfaction with care provision. Cross-sectional study designs are valuable for providing descriptive information about prevalence and avoid problems related to resources needed to undertake the research, such as time and money, and the potential dropout problems of studies that require follow-up. Cross-sectional studies do not provide evidence for causality. An observation made in the cross-sectional study in this thesis is the possibility of side effects of anticancer treatment worsening over time. This warrants future study, for example, a longitudinal cohort study. Qualitative studies may also be useful in understanding the impact of cancer on managing other multiple conditions and vice versa and the impact of psychosocial problems on the ability of older cancer survivors to self-manage.

Explore the effectiveness of combining the realist approach with behavioural science

Chapter 4 described the novel approach of combining the realist review with the TDF, a behavioural framework. The realist review in Chapter 4 is the first reported study to use an *a priori* behavioural framework to inform development of initial programme theories. This approach was used to identify a broad range of determinants on healthcare practitioner behaviour than would be possible using empirical evidence alone. As more studies emerge using this approach, it may be beneficial to explore whether this approach consistently

achieves broad coverage of determinants. Combining realist methods with behavioural science could be beneficial in advancing future approaches to intervention development.

Developing a set of outcomes for self-management support in cancer survivors

Chapter 2 introduced the logic model for this thesis. The contributions made by Chapters 3 to 5 in populating the different parts of the logic model were summarised at the end of each chapter and are shown in Figure 26. However, identifying outcomes for the intervention was beyond the scope of this PhD. An outcome is a measurement or observation to assess the effectiveness of a treatment or intervention [260]. Despite self-management support receiving growing attention, little is known about which outcomes are important to patients, practitioners, organisations and the health system [261]. Appropriate outcome selection, measurement and reporting are important for designing quality research studies [260]. To address the lack of a set of outcomes for self-management support interventions in the cancer survivorship setting, development of a core outcome set is recommended. Adoption of a core outcome set will ensure that self-management support outcomes that are considered important by cancer survivors, practitioners and policy makers are assessed as a minimum in future studies. Routine use of a standardised set of outcomes may enable comparison of self-management support interventions delivered to cancer survivors to optimise quality and usefulness of these interventions.

Further refinement of the intervention developed in this thesis

The research described in this thesis to develop an intervention to facilitate practitioners in general practice to deliver self-management support to older cancer survivors has completed two of the three steps of the development phase of UK MRC guidance for developing and evaluating complex interventions [88]. The first two steps, ‘Identifying the evidence base’ and ‘identifying and developing theory’ have been completed. Further work is recommended to complete the final ‘Modelling process and outcomes’ step to refine the intervention

developed in this thesis and develop a prototype intervention before a full-scale pilot and evaluation can be planned.

6.4.3 Policy

Embedding self-management support into routine cancer survivorship care will require a whole-system change [75]. This will need trained and skilled healthcare practitioners, systems and processes to ensure the needs of cancer survivors are appropriately addressed and changes to overcome any organisational and system-level barriers for implementing self-management support. The recommendations for policy-makers arising from this thesis are illustrated below:

Incentivise primary care teams to deliver self-management support to cancer survivors

Reimbursements or incentives will be key to facilitating delivery of self-management support interventions in primary care. The Quality and Outcomes Framework financially rewards general practices in the NHS in England for delivering effective interventions for long-term conditions and achieving evidence-based patient outcomes [262]. Recent changes to the Quality and Outcome Framework cancer indicators that recognises the key role played by primary care in supporting people with a cancer diagnosis are welcomed [236]. However, the Quality and Outcome Framework indicators are limited in that they focus on single long-term conditions [262]. Given that many cancer survivors also have other long-term conditions, policy-makers in the NHS should consider reviewing the Quality and Outcome Framework indicators to improve care for people with complex needs. Provision for elements of care prioritised by the NHS Long-term plan, such as, coordinated and integrated care, personalised and holistic care and self-management support should be considered. Policy-makers could also consider alternative methods for rewarding good practice.

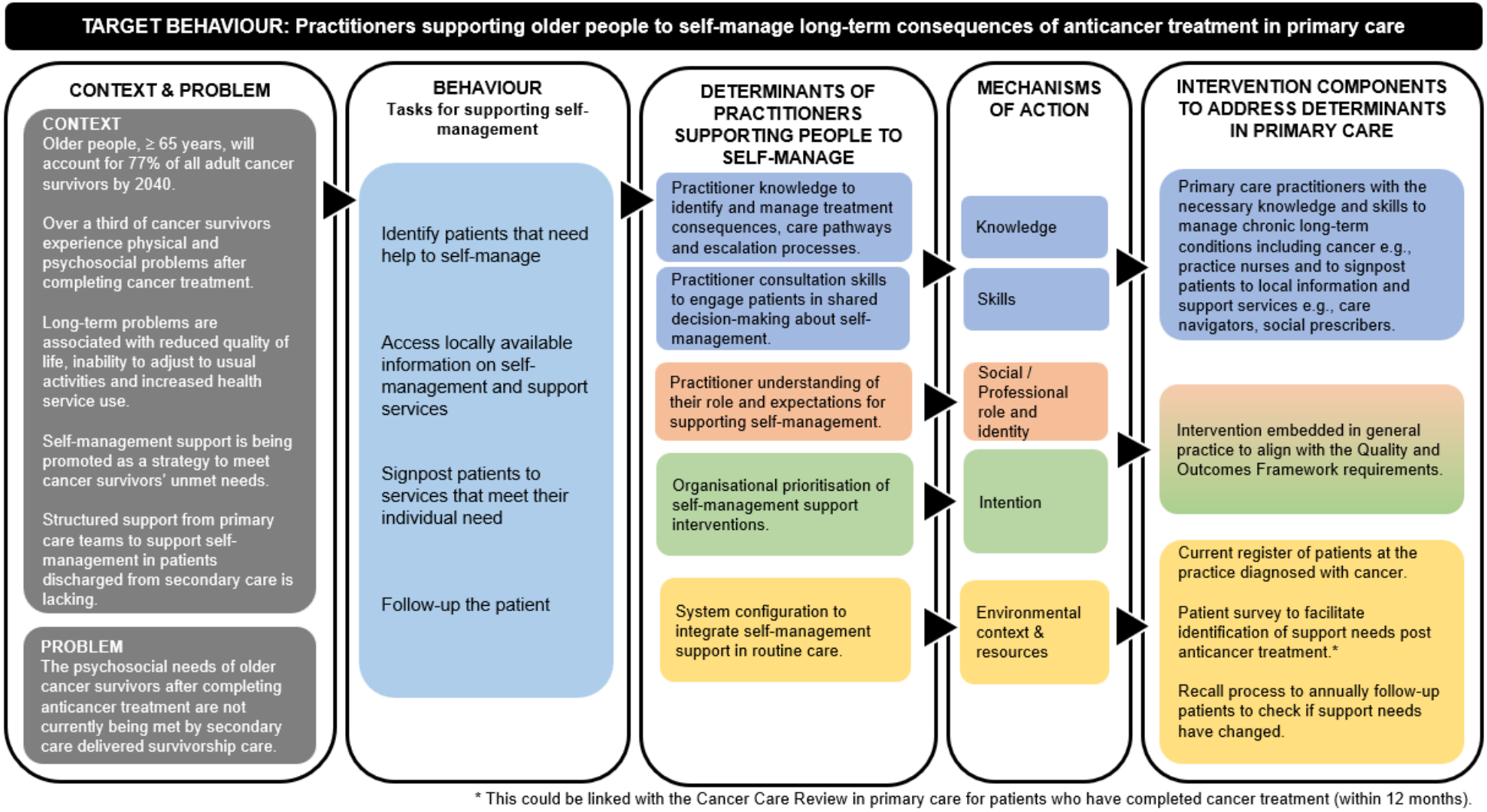

Figure 26: Logic model for facilitating practitioners to deliver self-management support in general practice in the NHS in England

6.5 Personal reflections

The reflections included below relate to my overall PhD journey, using a realist approach to evidence synthesis, conducting co-design during a pandemic and overall experience of cancer survivors.

6.5.1 Overall PhD journey

The key highlights along my PhD journey have been securing external funding to support the research and the opportunities to share and disseminate some findings of the research.

I secured external funding for all three empirical studies from Pharmacy Research UK, which facilitated peer review of the studies, giving me reassurance of the robustness of the methods. The final reports that I produced at the end of the studies were approved after a peer review process, again giving me reassurance that the research integrity was upheld and was of good quality. Additionally, publication of the protocol for the study reported in chapter 4 was a pivotal moment and suggested that my study was valid, significant and original. The valuable feedback I received via the peer review process in scientific publications further allowed me to refine the method and improve the quality of the study reported in Chapter 4. Securing competitive funding from Pharmacy Research UK allowed adoption of studies reported in Chapter 3 and 5 on to the national portfolio of the National Institute for Health Research. Portfolio adoption facilitated recruitment of participants from multiple organisations and across a wide geography. Support from the Eastern Clinical Research Network allowed the studies reported in Chapters 3 and 5 to exceed recruitment targets and were completed within the proposed timescales.

I have also seized opportunities to present my research. The two notable examples are a poster presentation at the 2019 International Society of Geriatric Oncology conference and an oral presentation at the virtual 2021 International Realist conference. The reasons these

two conferences stood out for me were the opportunities that arose from attending the International Society of Geriatric Oncology conference and the chance to present my realist review to an expert international audience of realist researchers. I was invited to be part of the International Society of Geriatric Oncology COVID-19 working group, which has resulted in two publications related to adapting care and vaccine roll-out for older cancer patients during the pandemic. My key contribution for the paper on adapting care was to include a section on the care of older cancer survivors. Using the TDF to guide programme theory development in realist reviews was novel. The abstract submitted describing the method was selected for an oral presentation at the International Realist conference held in February 2021, which signified the novelty of the approach and its potential to advance realist methodology.

6.5.2 Realist review

Realist reviews are increasingly being used for assessing complex interventions. However, doing a realist review requires considerable commitment from a novice reviewer to understand the language and principles of realism and the process to carry out the review. A step by step process for doing realist reviews exits [96], however, making sense of the language and principles of realism was more challenging. Ray Pawson and Nick Tilley, the 'fathers' of scientific realism, have written widely about the approach [109, 263], much from a social science perspective. I found the language used by Pawson and Tilley inaccessible, for the most part. Attending training to understand the methodology and carry our realist reviews was more beneficial. Additionally, acquiring a mentor with extensive expertise in doing realist studies was helpful in understanding the underlying philosophy and principals of realism.

One of the first challenges was to develop realist programme theories. This took considerable reading about the experiences of cancer survivors with respect to self-management and self-management support. Most of the draft initial theories developed were discussed with the mentor, who advised further refinement. The mentor advised to ask,

“what is it about” self-management interventions in cancer survivors that make them work or not? to get a deeper understanding of the interventions. It was only when my supervisory team suggested using the TDF to guide programme theory development that I made progress with developing draft programme theories. Programme theory development using the TDF involved becoming familiar with the 14 domains and using the TDF to identify the factors that influenced provision of self-management support by practitioners, based on published literature and my experience as a cancer pharmacist. This allowed a stepwise method to developing programme theories. A total of 22 programme theories were developed, across the 14 domains of the TDF. Testing all 22 programme theories was not possible given the time assigned for completing the realist review. Stakeholder involvement was invaluable in narrowing down the programme theories to less than half. Ten programme theories were tested against the published literature in the realist review reported in Chapter 4. The next step was to do a database search. This followed the same methods used for searching employed in traditional systematic reviews. Evidence searching and selection were also similar to methods used in traditional systematic reviews, except selection was focussed on identifying contexts, mechanisms and outcomes. Data extraction and synthesis involved discussions with the review team, leading to refinement and finalisation of the five programme theories presented in Chapter 4.

6.5.3 Co-design during the COVID-19 pandemic

Workshop planning

Originally a face-to-face co-design study was planned for this thesis. But, in March 2020, when the protocol for the co-design study was being written, the World Health Organisation declared a global COVID-19 pandemic. The options were to either wait for the pandemic to end and continue with the planned face-to-face study or rethink how the co-design study could be conducted during the pandemic. As there were too many uncertainties about COVID-19, option one was not feasible within the timeframe of the PhD. The co-design study was therefore modified to be conducted online.

At the beginning of the pandemic, there was little guidance for conducting online co-design workshops. I therefore modified the protocol for the co-design study based on my reading around conducting online meetings and online interviews and focus groups. I also needed to consider how to embed the key principals of co-design into the online space. The choices available for activities to support the design process were limited to those that could easily be done online and by all participants. Introducing activities that potentially required advanced computer skills or additional equipment were avoided, e.g., asking participants to type comments on virtual 'post-it' notes, or asking participants to produce drawings and sharing them online. I had participated in face-to-face co-design workshops in the past. However, planning and running a co-design workshop was new to me, and so was the added challenge of running online workshops.

Various changes were made to the co-design workshops to facilitate online discussions, and are listed here:

- The number of discovery workshops for healthcare practitioners was increased from two to three, to accommodate anecdotal recommendations that online workshops should not exceed ten participants.
- The duration of discovery and co-design workshops were capped at a maximum of two hours to minimise 'digital fatigue' for participants.
- The number of co-design workshops was increased from one half-day session to three two-hour sessions to enable the required material to be covered.
- The geography for recruiting practitioners was expanded from Norfolk to England-wide, as changing to online workshops overcame the challenges of excessive travel distances. The study was opened to recruitment across four Clinical Research Network regions in England: Eastern, East Midlands, South London and Yorkshire and Humber.

Running workshops

The three discovery workshops were run in January 2021, and the three co-design workshops were run in February and March 2021, one year after COVID-19 was declared a pandemic. All workshops were run on Microsoft Teams, an online hub for teamwork. By the time the workshops took place the research team and the practitioners involved in the workshops were using Microsoft Teams on a regular basis. The three patient participants were more familiar with Zoom, an online collaboration tool, but two had experience of using Microsoft Teams. All participants were invited to contact me in advance of the workshops if they needed support using Microsoft Teams, with only one patient requesting a practice session.

I was responsible for creating all the material for and delivering the workshops. This involved ensuring that consent forms were in place for all participants, sharing presentations to introduce workshops and summarise the aims and objectives, recording the workshops, time-keeping, monitoring the 'chat' in Microsoft Teams where participants were free to type comments to supplement the verbal discussions, providing instructions for and facilitating all activities, listening to discussions and seeking clarification or summarising key messages, allocating participants to 'break-out' rooms to facilitate smaller group discussions and bringing them back to the main discussion, and providing summaries at the close of each workshop. The research team were present to facilitate workshop discussions, provide input at debriefing sessions and guide planning for subsequent workshops. At times, having to multi-task during the workshops was overwhelming. It was challenging to follow both verbal discussions and those that were taking place simultaneously via 'chat.'

Some participants had 'technical issues', which remained unresolved throughout the session. For example, one participant could not use the 'video' function but was content to participate using audio, another participant could not use the 'chat' function. Finally, at the

workshop where small group discussions were planned, one participant could not be allocated to a 'break-out' room, which was resolved by me having a one-to-one discussion with the participant. In all cases, the 'technical issues' were related to the settings on the devices being used. Several participants were using devices that were usually used by their children for school, with some functions on Microsoft Teams disabled.

Technical problems were anticipated. To minimise the impact of technical problems, one member of the research team (DB) was assigned to resolve problems with participants. Further, activities were kept to a minimum number with additional time factored in, if needed, to resolve technical issues.

All workshops took place in the early evening, between 5-7pm, which seemed to be a good time for participants. Mini-breaks of about 10 minutes were planned about half-way through each workshop to ensure participants and the research team could attend to their comfort needs. Unlike in face-to-face workshops, where tea and biscuits are usually available throughout the workshops for participants, in online workshops the breaks need to be planned. Furthermore, with online meetings there is no guarantee that all participants will return after the break, which was not an issue for the co-design study in this thesis. No workshop ran beyond 7pm.

One of the key concerns in online co-design is ensuring that there is no power imbalance. The co-design study participants were a group of patients, a mix of practitioners and a commissioner. It is possible that in such a group, the practitioners could dominate the conversation, resulting in the patient voice going unheard. To minimise for this potential power imbalance the aims and objectives were made clear at the start of each workshop, with emphasis on a partnership approach. Further it was stressed that experiential knowledge was just as important as knowledge from published evidence or acquired during clinical practice. Introductions were made at the start of each session and everyone was

encouraged to use first names only. Skilled facilitation was important to keep all participants engaged throughout the two hours and was achieved by including interactive tasks. The patients who participated in the study were all active members of organisations to improve local cancer care and therefore engaged fully in the discussions and activities. The same participants took part in the three co-design workshops, which may have facilitated rapport building.

Online co-design was hard work. It took time and lots of planning to ensure that participants had an enjoyable experience. I hope that participants felt that they were making a meaningful contribution to improving the lives of older cancer survivors.

Opportunities presented during the pandemic

Unexpectedly, the pandemic also created opportunities for learning, and specifically in relation to realist methods. The pandemic necessitated a halt to all in-person events, including academic seminars, which are invaluable in facilitating learning and sharing of research among PhD students. Some universities in England involved in realist research, e.g., University of Leeds and University of Nottingham, switched in-person seminars to online webinars and opened them to anyone involved in realist research. This allowed me to tap into realist expertise on a regular basis. Attendance further developed my understanding of realist research methods and allowed learning from experiences of other PhD students and realist researchers. Examples of webinars that were particularly valuable were how to answer realist questions in a PhD viva and a study that embedded a realist review in a co-design study.

6.5.4 Experiences of cancer survivors

My understanding of experiences of cancer survivors, related to living with long-term problems of anticancer treatment, were shaped at the start and towards the end of my PhD journey. One of the tasks at the start of my PhD was to review the literature and key reports

related to cancer survivors to understand their experiences. Working as a cancer pharmacist, I had some knowledge of experiences of people during and on long-term maintenance anticancer treatment. However, my knowledge of experiences of cancer survivors after they completed anticancer treatment was limited. Extensive reading of the literature led to developing a framework of the influences on unmet needs of cancer survivors, which is described in section 1.5. This understanding helped to identify the aim of this PhD and shaped the three empirical studies described in this thesis.

The literature often describes the experiences of people after completing cancer using the metaphor of “falling off the edge of a cliff.” Cancer survivors are very vulnerable during this period as they face much uncertainty and fear about the cancer returning, and the frequency of support from secondary care healthcare practitioners starts to drop. During one of the discovery workshops, that I reported in Chapter 5, one of the participants said something that had ‘stuck’ with me. He said that older cancer survivors face a “double drop.” Not only do older cancer survivors feel unsupported after they complete cancer treatment but are left on their own to manage the consequences of cancer alongside other long-term conditions, while possibly facing the physical, functional and cognitive decline associated with normal ageing. Many older cancer survivors will not reach out for help and we need to do better at supporting them.

6.6 Conclusion

The research in this thesis has led to the development of an intervention to facilitate the general practice team in the NHS in England to deliver self-management support to older cancer survivors who have completed anticancer treatment. This was achieved using three studies: a cross-sectional study to estimate the prevalence of side effects of anticancer treatment in older cancer survivors and perceived satisfaction with care to manage them, a realist review of the evidence to understand the determinants to healthcare practitioners

delivering self-management support to cancer survivors and a co-design study with stakeholders to develop and design the intervention.

The key findings from the cross-sectional study were that although side effects from anticancer treatment impacted multiple domains of life in older cancer survivors, support for psychosocial needs were lacking. The study further highlighted that satisfaction with care from secondary care healthcare practitioners was lower after completing anticancer treatment than during treatment. Although the cross-sectional study suggested that overall wellbeing scores may be lower for patients who had completed anticancer treatment more than two years previously, this needs further exploration. Finally, the study showed that half of the older cancer survivors surveyed were able to effectively manage the long-term problems related to anticancer treatment. The implications of the cross-sectional study are that older cancer survivors need additional support to self-mange the psychosocial consequences of anticancer treatment, which may persist years after completing anticancer treatment. Older cancer survivors may also need ongoing support to manage psychosocial problems after they are discharged from secondary care.

The realist review, underpinned by a theoretical framework, identified five inter-dependent determinants involved in facilitating practitioners to provide self-management support, at the healthcare practitioner level, healthcare practitioner-patient level, organisational level and system level. This implied that developing a practitioner behaviour change intervention to facilitate delivery of self-management support will depend on addressing the determinants at these multiple levels.

The co-design study confirmed that determinants identified in the realist review were applicable to the primary care context in the NHS. The co-design study further identified four tasks that primary care teams should undertake to support older cancer survivors to self-manage. During the co-design process the general practice setting was identified as the

better location for the intervention compared to community pharmacies, based on the existing resources, processes and infrastructure in general practice. The study set out to develop an intervention to support older cancer survivors, however, co-design stakeholders suggested that the intervention could benefit all adult cancer survivors.

The intervention developed in this thesis enables general practice teams to play a proactive role in providing personalised care and support to meet the unique needs of the cancer survivors within their communities. The intervention requires optimisation and refinement through modelling to develop a prototype for future testing. A feasibility study of the optimised intervention is required to determine whether it is effective and cost-effective in supporting cancer survivors to self-manage long-term consequences of cancer and its treatment. If the intervention is shown to be effective in a definitive trial, then large scale roll-out to general practices in England may be appropriate. Adaptations of the intervention will likely be needed to account for availability of local resources, processes and infrastructure.

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Appendix A. Study protocol for Chapter 3

CaSES Service Evaluation Summary

Cancer Side Effect Support for older people – CaSES

Service evaluation of the extent to which older people attending follow up cancer clinics are supported to manage anticancer treatment side effects

Contents

1. Introduction

People aged 65 years and older represents the largest group of patients diagnosed with cancer in the UK[1]. By 2030, there will be an estimated four million people in the UK living with the long-term consequences of cancer[2]. With the number of cancer cases projected to rise due to rapid ageing of the UK population, there is growing consensus on the need for new research, policies and strategies to improve the evidence base for treating older adults.

The 2015 Cancer Strategy for England[3] highlighted that the needs of older people with cancer are poorly understood. In November 2018, the National Cancer Research Institute[4] identified a top research priority as being the development of models for managing the long-term consequences of cancer and its treatment. The current project is part of a programme of research to develop an intervention to support older people living with and beyond cancer to self-manage the long-term consequences of systemic anticancer therapy.

The first part of this research programme (Phase 1) is establishing the patient experience and gaps of current service provision. Phase 1 of the research programme is a service evaluation of the impact of systemic anticancer therapy side effects on older people living with and beyond cancer and the extent to which existing oncology services are supporting older cancer patients to manage their systemic anticancer therapy side effects.

Systemic anticancer therapy (SACT) refers to any drug that stops cancer cells from reproducing or spreading and includes traditional cytotoxic drugs, newer 'targeted' or biological therapies, immunotherapies, and hormone therapies. SACT-related side effects can persist for many years after completion of treatment (long-term effects) and some can present months to years after finishing treatment (late effects)[5]. Long term and late effects of SACT can include physical complications, psychological symptoms and functional decline and are associated with poor treatment adherence, treatment delays, increased hospitalisation, increased health costs, reduced quality of life and fatal consequences[6-8].

The effect of SACT on older survivors is understudied due to the underrepresentation of older people and exclusion of people with comorbidities in cancer clinical trials[9,10]. Not only do older people with cancer have poorer health outcomes, functional status and quality of life compared to those without cancer[9,11,12], but the severity of side effects in older survivors is different compared to younger adults[13]. The lived experiences of older cancer survivors is often complicated by other comorbid conditions; as many as 70% of cancer patients have at least one other long-term condition and over a quarter have at least three other long-term conditions[3].

Further phases of the programme explore the realist programme theory development and synthesis to understand what works for whom and in what circumstances in relation to self-management interventions delivered in primary care to support cancer survivors to manage the long-term physical and psychosocial consequences of SACT. Focus groups will be convened to validate the realist programme theory and development of the model for self-management support for older cancer survivors in the community by synthesising data from the previous phases to formulate an evidence and theory–based intervention.

The purpose of the CaSES service evaluation is to understand what support is currently available to older cancer survivors to manage SACT side effects to inform future service provision in the NHS.

2. Aims:

To evaluate the impact of SACT side effects on older people living with and beyond cancer and the extent to which existing oncology services are supporting older cancer patients to manage SACT side effects.

3. Objectives:

i. Explore the physical and psychosocial impact of SACT-related toxicities on older people living with and beyond cancer.
ii. Identify the healthcare professionals and others that support older people with their SACT-related physical and psychosocial problems.
iii. Assess older peoples' satisfaction with follow-up cancer care with respect to physical, emotional and social problems.
iv. Explore the impact of SACT-related toxicities on the ability of older people to self-manage ongoing problems of cancer or cancer treatment.
v. Evaluate the impact of SACT-related toxicities on older peoples' ability to adjust to life after cancer treatment.

4. Methods:

4.1 Service evaluation approval

Prior to the commencement of the service evaluation, approval must be sought to administer a patient survey from the research governance departments of participating sites. The CaSES study has been reviewed by the ethical committee of the Faculty of Medicine and Health Sciences (FMH), University of East Anglia (UEA) and the CaSES study has been approved as a service evaluation (Reference 201819 – 008).

The survey (Appendix 1) will be administered by any patient-facing member of the participating site research team who is GCP trained and named on the site Delegation log (Appendix 2).

Each site will appoint a Study Lead. The study lead can be a medical consultant or from a non-medical background e.g. nursing, allied health professionals, psychologists. The study lead will be responsible for all the day-today study-related activities performed at the site and will facilitate timely recruitment.

The participating site survey team will be responsible for administering the survey and accessing routinely held patient data to record cancer treatment details and confirm that primary cancer treatment was completed.

4.2 Participants

Participants will be from multiple cancer centres in England. Patients will be recruited from the breast cancer, colorectal cancer and prostate cancer follow-up outpatient clinics. The patients will have completed primary cancer treatment up to two years previously and/or receiving long-term maintenance treatment e.g. hormonal treatment.

4.3 Sampling

The sample size will be approximately 300 patients across multiple hospital sites – minimum of 50 patients per site. Assuming an equal distribution of survey responses, a sample size of 300 participants will provide a 95% confidence interval of ± 4.9% around the impact of chemotherapy side effects on the quality of life of older people living with and beyond cancer.

Patients will be identified from the follow-up clinic lists and meet the criteria below:

Inclusion criteria

- Patient age 65 and over
- Solid tumour diagnosis (breast, colorectal or prostate cancers) and treated with anticancer treatment (included cytotoxic drugs, targeted therapies and anti-hormone drugs)
- Patient in the follow-up cancer clinic
- Patient diagnosed with cancer up to 24 months previously

Exclusion criteria

- Patients approaching the end of life (people in their last year of life)
- Patients with mental health problems
- An older person living with severe frailty (e.g. electronic frailty index > 0.36) i.e. people dependent for person care and have a range of long-term conditions/multimorbidity who may be stable or unstable and at risk of dying within 6 – 12 months[14]
- Patient does not speak, read or understand English

4.4 Participant identification

The site survey team will identify patients in the cancer follow-up clinics that meet the inclusion criteria. The survey team will approach the patient, explain the reason for the survey and what will be involved. A flyer will be available, which provides information about the survey (Appendix 3). The survey team will answer any questions from prospective participants, before they agree to complete the survey, if required.

If the patient decides to participate in the survey, one member of the survey team will administer the survey as described in section *4.5 Data Collection*, below. The survey team will record routinely held participant details on the Recruitment log (Appendix 4). The recruitment log will be referred to throughout the service evaluation period to ensure patients who do not wish to be involved are not approached and patients who have already participated are not re-approached. This Recruitment log will be kept in the participating hospital site during the data collection period and thereafter destroyed at the end of the service evaluation, as instructed by the CaSES study team.

4.5 Data collection

A survey will be administered in the cancer outpatient follow-up clinics. The survey will be administered using Online Surveys (formerly BOS, Bristol Online Surveys) on an electronic tablet device. Online Surveys is a recommended forms platform by UEA to ensure compliance with the General Data Protection Regulation (GDPR) requirements.

In accordance with NHS hospital Trust infection control procedures, only the survey team will handle the tablet device. The survey team will position the device to allow the participant to read questions and vocalise answers. The use of a tablet device will allow the font size of the questions to be adjusted, as necessary, for the requirements of the participant. A hard copy of the questions will be available for those patients who prefer to read questions from a paper copy of the survey. The participant's response for each question will be selected by the survey team on the tablet device. The survey team will vocalise questions and / or participant responses, if requested. After the survey is completed, the survey team will update the Recruitment log, to include survey completion date and where not completed, the reason for not completing the survey (Appendix 4).

The survey includes a mix of Likert scale questions, open questions and demographic details such as participant age, cancer type and living arrangements.

4.6 Survey

As there are no validated surveys exploring older cancer survivors' views of the impact of anticancer treatment side effects on their lives, we have developed a short survey (Appendix 1).

The survey includes the following sections:
Section A: Your experience of anticancer treatment side effects and support from cancer services (17 questions)
Section B: Getting information and support for anticancer treatment side effects (1 question)
Section C: Your overall wellbeing (1 question adapted from Locke et al[15])
Section D: Other comments (3 open questions)
Section E: About you (2 questions)

The survey has been kept short to minimise survey burden on older cancer patients. Commonly employed instruments exploring cancer survivors quality of life and experiences of care tend to be lengthy e.g. EORTC QLQ has 30 questions[16].

The academic team at UEA have developed the survey, with input from people living with and beyond cancer. To ensure face and content validity of the survey, we have incorporated comments from the Together Against Cancer (TAC) group (part of the Big C cancer charity in Norfolk) and through cognitive interviews ('think-aloud' exercise).

4.7 Ethical considerations

a. Informed consent

All participants will be informed about the following:

- Explanation of why the service evaluation is taking place
- Outline the key aims and objectives
- Assure respondents of confidentiality and anonymity
- Explain how the information will be used
- Explain how respondents can receive information about the service evaluation
- Explanation that respondents are under no obligation to take part in the survey. Their decision to participate or not will not affect the standard of care they will receive from the follow-up cancer clinics

- Explanation that choosing to agree to complete the survey will be viewed as consent to participate in the survey. By submitting responses, respondents agree that the survey team can use the data collected for the purposes described above. As respondents will not be identifiable in the survey evaluation, withdrawal of consent will not be possible after submitting the survey.

b. Contact

A UEA postgraduate researcher, Kumud Kantilal, will be available should any participating site survey team member need clarification on the survey. Alternatively, the postgraduate researcher's supervisors may be contacted via email if needed: Dr Debi Bhattacharya D.Bhattacharya@uea.ac.uk and Dr Wendy Hardeman W.Hardeman@uea.ac.uk

c. Confidentiality and anonymity

Respondents will not be asked to provide any personally identifiable details for the online survey so participant confidentiality and anonymity will be maintained.

d. Data storage

No identifiable patient information will leave the participating site premises. Data management will follow the 2018 General Data Protection Regulation Act and the University of East Anglia Research Data Management Policy (2015). Respondent identity/information will be kept strictly confidential and stored at each participating site securely and accessible to the local survey team only, except as required by law. Anonymised data will be stored on UEA computers, password protected and accessible only to the study team at UEA, for a period of 10 years and then destroyed.

Each participating site will provide the CaSES study team with anonymised copies of Recruitment logs. After confirmation of receipt of the Recruitment logs by the CaSES study team, the participating site can destroy the Recruitment logs, but no later than six months form the publication of the study final report.

Survey findings may be published, but respondents will not be identified in publications.

e. Information on results

Participating sites will be informed about how and when they can access results of the service evaluation. The feedback will be presented in a way that is accessible and easy to understand and tailored to the needs of respondents. Respondents wishing to be informed about the results will be asked to contact a member of the participating site survey team at the end of the service evaluation, i.e. after June 2019. Data will not be able to be linked to the participant's email address as the survey is anonymous.

4.8 Feedback to participating organisations

A report presenting the survey findings and discussing recommendations for improvement and future research will be prepared.

4.9 Time line

The proposed timeframe for the service evaluation is included below:
Service evaluation UEA ethics approval: October 2018
Data collection: November 2018 – March 2019
Analysis: April – May 2019
Final Report produced: June 2019

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Appendix 1: Survey

Cancer Side Effect Support for Older People – CaSES survey

Together with staff at the hospital, we are interested in finding out how things are for you in relation to anticancer treatment side effects. We also want to know about your experiences of attending the cancer clinics. Our aim is to understand your experience of how well we are doing in the cancer clinic to help you manage side effects of anticancer treatment and make improvements based on your feedback.

Participation in this survey is voluntary.

By completing the survey, I state that:

- ✔ I understand the purpose of the study and what I will be asked to do.
- ✔ I have been able to discuss my involvement in the study with the survey administrators (people handing out the survey) if I wished to do so.
- ✔ The survey administrators have answered any questions that I had about the study and I am happy with the answers.
- ✔ I understand that being in this study is completely voluntary and I do not have to take part. My decision whether to be in the study will not affect my current care or relationship with the health care professionals at the hospital and the survey administrators or anyone else at the University of East Anglia now or in the future.
- ✔ I understand that if I decide to take part in the study and then change my mind, I am free to withdraw at any time before I have completed answering the survey. Once I have completed the questions, my responses cannot be withdrawn because they are anonymous and therefore the survey administrators will not be able to tell which one is mine.
- ✔ I understand that personal information about me that is collected over the course of this survey will be stored securely and will only be used for purposes that I have agreed to. I understand that information about me will only be told to others with my permission, except as required by law.
- ✔ I understand that the results of this survey may be published, and that publications will not contain my name or any identifiable information about me.

I agree to completing this survey ☐ Yes ☐ No

The information that you give us will be kept anonymous. We will not pass the information on to the healthcare team at the hospital. This means you do not have to write your name on the questionnaire, and that all information will be treated confidentially.

Please read each question carefully. There are no right or wrong answers to these questions. You may find some of the questions feel personal. These questions help us to better understand what kind of care you need. If you decide there are any questions you do not want to answer, please go to the next question.

The CaSES survey is led by the Schools of Pharmacy and Health Sciences, University of East Anglia. Our team is working with healthcare professionals and patient representatives at Norfolk and Norwich University Hospital and Guy's Cancer Centre. We are responsible for the survey design, conduct, data analysis and interpretation and dissemination of results.

If you have any comments or questions about the survey please feel free to contact Kumud Kantilal (01603-591973).

Participant eligibility check - For office use only

Survey administrator to complete the following information before proceeding to the survey questions.

Site name: _____

Participant number: _____

Participant age (years): _____

Participant sex

- ☐ Male
- ☐ Female

Participant cancer type

- ☐ Breast
- ☐ Bowel
- ☐ Prostate

Cancer Side Effect Support for Older People – CaSES survey

This survey is about your experience of anticancer treatment and the support you get to manage any problems. Anticancer treatment includes medicines used to destroy cancer cells or affect the way they grow and divide. These medicines could be given to you in the hospital or used at home, such as injections, tablets or capsules.

We want to know whether you are getting the support you need from us to manage any problems with your anticancer treatment.

When we use the words 'us' or 'staff' we mean all the staff in the hospital or anyone or services they may have referred you to.

What you tell us will help us find out whether we need to change what we are doing.

SECTION A: Your experience of anticancer treatment side effects and support from cancer services

In this section we want you to think about any side effects that you think have been caused by your anticancer treatment. We also want to know how supported you felt to manage these side effects.

1. **Over the last MONTH have you had any side effects that you think are caused by your anticancer treatment?**

☐ Yes
If Yes, please describe your experience:

☐ No
If No, please go to Section B

2. **In the last MONTH, how much have your anticancer treatment side effects affected:**

2.1 Your physical health?
e.g. urinary, bowel, fatigue problems, feeling/being sick

☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always

2.2 The staff have supported me with managing these physical problems.

☐ Strongly agree ☐ Agree ☐ Neither ☐ Disagree ☐ Strongly disagree

2.3 Your emotional well-being?

e.g. anxiety , fear, worry, anger, depression, coming to terms with thinking of yourself in a different way

☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always

2.4 The staff have supported me with managing these emotional / psychological problems.

☐ Strongly agree ☐ Agree ☐ Neither ☐ Disagree ☐ Strongly disagree

2.5 Your social life?

e.g. return to work, benefits, insurance, returning to your normal activities

☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always

2.6 The staff have supported me with managing these social problems.

☐ Strongly agree ☐ Agree ☐ Neither ☐ Disagree ☐ Strongly disagree

2.7 Your relationships with family and friends?

e.g. family arguments, difficulty in talking about relationships, intimacy issues, lack of interest in sex, feeling unloved or unlovable

☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always

2.8 The staff have supported me with managing relationship problems with family and friends.

☐ Strongly agree ☐ Agree ☐ Neither ☐ Disagree ☐ Strongly disagree

2.9 Your ability to deal with any problems related to cancer or anticancer treatment?

☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always

2.10 The staff have helped me to deal with any problems related to cancer or anticancer treatment.

☐ Strongly agree ☐ Agree ☐ Neither ☐ Disagree ☐ Strongly disagree

2.11 Your ability to manage other long-term conditions?

e.g. high blood pressure, diabetes, heart problems, arthritis, etc.

☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always

2.12 The staff have supported me with managing other long-term conditions.

☐ Strongly agree ☐ Agree ☐ Neither ☐ Disagree ☐ Strongly disagree

2.13 Your ability to adjust to life after cancer treatment?

e.g. returning to your daily routine and usual activities

☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always

2.14 The staff have supported me with adjusting to life after cancer treatment.

☐ Strongly agree ☐ Agree ☐ Neither ☐ Disagree ☐ Strongly disagree

3. Overall, how satisfied are you with the general support and care you received during your anticancer treatment?

☐ Very dissatisfied ☐ Dissatisfied ☐ Neither ☐ Satisfied ☐ Very satisfied

4. Overall, how satisfied are you with the general support and care you received after completing your anticancer treatment?

☐ Very dissatisfied ☐ Dissatisfied ☐ Neither ☐ Satisfied ☐ Very satisfied ☐ Not yet completed anticancer treatment

SECTION B: Getting information and support for anticancer therapy side effects

In this section, we want you to think about where you get information and support to manage side effects related to anticancer treatment.

5. When you get any side effects from anticancer treatment, who do you turn to or where do you go for information and support to manage them?

Tick all that apply

5.1 Your oncologist (hospital cancer doctor) ☐
5.2 Your clinical nurse specialist (hospital cancer nurse) ☐
5.3 Your hospital nurse (nurse in the cancer outpatient department or chemotherapy / cancer day unit/acute oncology service (AOS)) ☐
5.4 Your GP ☐
5.5 Your practice nurse (nurse in the GP surgery) ☐
5.6 Other health professional(s) ☐
e.g. pharmacist, physiotherapist, dietician, psychologist
Please tell us who this is:

_____

5.7 Other professionals ☐
e.g. complementary therapist
Please tell us who this is:

_____

5.8 Your friends ☐
5.9 Your family ☐
5.10 The internet ☐
e.g. Macmillan website, Big C website, Hospital website, Cancer Research UK website
5.11 I did not contact anyone / seek out any information. ☐
Please tell us why:

I did not need any support or information ☐
I did not know who to ask ☐
I did not know where to look for information ☐
I did not want to bother the staff ☐
Other – please explain ☐

_____

_____

_____

SECTION C: Your overall wellbeing

The question in this section is about your wellbeing and how you felt over the past week.

6. How would you rate your overall wellbeing over the past week?

1	2	3	4	5
As good as it can be				As bad as it can be

SECTION D: Other comments

We would like to know what we are doing well and how we can improve the service that we are providing. We will remove any information that could identify you.

7. **Is there anything that we can improve to better support you in managing side effects of anticancer treatment?**

8. **Is there anything particularly good about the support you have had to manage side effects of anticancer treatment?**

9. **Any other comments?**

SECTION E: About you

This section is about your background. This information will help us analyse and organise your results.

10. Which statement best describes your living arrangements?
    - ☐ I live with partner/spouse/family/friends
    - ☐ I live alone
    - ☐ I live in a nursing home, hospital or other long term care home
    - ☐ Other (please tell us where)

11. Do you have health condition(s), other than cancer?
    - ☐ Don't know
    - ☐ No
    - ☐ Yes (if yes, please list these health conditions below)

Other health conditions:

<u>Paper version</u>: Someone will help you to fill out this survey electronically. Please ask a member of the outpatient clinic team.

<u>Online version</u>: Thank you for taking the time to complete this survey.

Appendix 2: Site Delegation Log

Cancer Side Effect Support for older people – CaSES

Service evaluation of the extent to which people attending follow up cancer clinics are supported to manage anticancer treatment side effects

Delegation and Signature Log

This log documents the study responsibilities I have delegated to colleagues involved in the conduct of the CaSES study at this site. I confirm that they have appropriate levels of qualification and experience and have been adequately trained to carry out their study responsibilities and in accordance to the principles of ICH GCP. Nonetheless, I confirm that, as the study lead I remain accountable for all study-related activities performed at this site.

Study Lead (SL): (Name and Signature)		**Edge ID No:**	**119657**
CPMS No:	**40736**	**Sponsor:**	**University of East Anglia**
Site Name:		**Site ID:**	

Name	Study Role[1]	Key delegated study tasks[2]	Duration (DD/MM/YYYY) From	Duration (DD/MM/YYYY) To	GCP expiry date	Signature	SL Signature and date

[1]**Study role codes:**

SL	Study Lead	**SC**	Study Coordinator	**RP**	Research practitioner				
RN	Research Nurse	**RA**	Research Assistant /Associate/Administrator	**CTA**	Clinical Trials Assistant /Associate/Administrator				

[2]**Delegated Study tasks:**

1	Determine eligibility	3	Online survey administration	5		7		9	
2	Obtain consent	4	Data collection from notes	6		8		10	

Appendix 3: Survey flyer

University of East Anglia

How can we improve cancer services for older people with ongoing side effects after finishing chemotherapy?

Help us understand:

- **The impact of ongoing chemotherapy side effects on your everyday life.**
- **How we can improve our outpatient services to support you to manage any side effects better.**

What do I need to do?

You will need to fill out a survey. This will take about 10 -15 minutes to do.

Whose thoughts and opinions do we want?

We want to hear from you if you are 65 years or older and have breast cancer, bowel cancer or prostate cancer.

Why is this important?

- By sharing your experiences, we can learn how to improve the care that people receive in the future.
- We will use your experiences to improve the support we offer to manage any ongoing chemotherapy side effects people may experience.

Where can I get more information?

Please ask a member of the outpatient clinic team. They will put you in touch with the right people who can give you more information.

Trust logo

Appendix 4: Recruitment Log

Cancer Side Effect Support for older people – CaSES

Recruitment Log

Service evaluation of the extent to which people attending follow up cancer clinics are supported to manage anticancer treatment side effects

Site name: _____ **Site ID:** _____

Participant no.	Participant Hospital no.	Participant Surname	Participant Name	Survey completion date DD/MM/YY *If not completed – include reason	Participant Age in years	Participant Gender M = Male F = Female	Cancer type B = Breast C = Colorectal P = Prostate	Treatment type Ch =chemotherapy R = Radiotherpay S = Surgery	Primary treatment completion date DD/MM/YY	*Reason for not completing survey (see codes below)
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										

* **Code for not completing survey: A** = Declined to participate in survey; **B** = Missed due to resource limitations

Appendix B. Ethical and site approvals for Chapter 3

Faculty of Medicine and Health Sciences Research Ethics Committee

Kumud Kantilal
PHA

Research & Innovation Services
Floor 1, The Registry
University of East Anglia
Norwich Research Park
Norwich, NR4 7TJ

Email: fmh.ethics@uea.ac.uk

Web: www.uea.ac.uk/researchandenterprise

23 October 2018

Dear Kumud

Project Title: Service evaluation of the extent to which older people attending follow up cancer clinics are supported to manage chemotherapy side effects
Reference: 201819 - 008

I have reviewed the submission of your above proposal and I can confirm that it is considered to be a Service Evaluation. There are no issues of confidentiality or harm to participants and I am happy to approve the study by light touch review.

Please could you ensure that any amendments to either the protocol or documents submitted are notified to us in advance and also that any adverse events which occur during your project are reported to the Committee. Please could you also arrange to send us a report once your project is completed.

Approval by the FMH Research Committee should not be taken as evidence that your study is compliant with GDPR and the Data Protection Act 2018. If you need guidance on how to make your study GDPR compliant, please contact your institution's Data Protection Officer.

I would like to wish you good luck with your project.

Yours sincerely,

Professor M J Wilkinson
Chair
FMH Ethics Committee

CC Supervisor
Project officer & REN project code (if we have this information)

Faculty of Medicine and Health Sciences Research Ethics Committee

Kumud Kantilal
PHA

Research & Innovation Services
Floor 1, The Registry
University of East Anglia
Norwich Research Park
Norwich, NR4 7TJ

Email: fmh.ethics@uea.ac.uk

Web: www.uea.ac.uk/researchandenterprise

18 February 2019

Dear Kumud

Project Title: Service evaluation of the extent to which older people attending follow up cancer clinics are supported to manage chemotherapy side effects

Reference: 201819 - 008

Thank you for your e-mail dated 21 January 2019 notifying us of the amendments you would like to make to your above proposal. These have been considered and we can now confirm that your amendments have been approved.

Please can you ensure that any further amendments to either the protocol or documents submitted are notified to us in advance, and also that any adverse events which occur during your project are reported to the Committee.

Approval by the FMH Research Committee should not be taken as evidence that your study is compliant with GDPR and the Data Protection Act 2018. If you need guidance on how to make your study GDPR compliant, please contact your institution's Data Protection Officer.

Please can you also arrange to send us a report once your project is completed.

Yours sincerely,

Professor M J Wilkinson
Chair
FMH Ethics Committee

Our Vision
To provide every patient with the care we want for those we love the most

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Miss Kumud Kantilal
School of Pharmacy
University of East Anglia
Norwich Research Park
Norwich
NR4 7TJ

Please reply to: Research and Development Department
Level 3, East Block, Room 032
Norfolk & Norwich University Hospitals NHS Foundation Trust
Colney Lane
Norwich
Norfolk
NR4 7UY
Direct Dial: 01603 287408
Internal: 3408

e-mail: rdoffice@nnuh.nhs.uk
Website: www.nnuh.nhs.uk

31st January 2019

Dear Kumud,

RE: 201819 (177-12-18)

Project Title: CaSES -Service Evaluation of Cancer Side Effect Support for Older People

This letter acknowledges receipt of the documents containing to the above project which has been received by the Norfolk & Norwich University Hospital NHS Foundation Trust Research & Development Office. This project is a service evaluation and not a research project, but has been accepted onto the NIHR portfolio and will be supported on EDGE. We have no objection to the project being undertaken within the Trust.

If you wish to discuss further, please do not hesitate to contact me.

Kind regards

pp. Dr Sally Burtles
Interim Director of Research Operations

Our Vision
To provide every patient with the care we want for those we love the most

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Norwich Radiology Academy
Cotman Centre
Norfolk and Norwich University Hospital
Colney Lane
Norwich
NR4 7UB
Direct dial: 01603 286154
Direct fax: 01603 286146
email: stuart.williams@nnuh.nhs.uk

Our Ref: SMW/mj

16 January 2018

Kumud Kantilal
Postgraduate Researcher
School of Pharmacy
Faculty of Science
University of East Anglia

Dear Kumud

Re Project: Service evaluation of the extent to which older people attending follow up cancer clinics are supported to manage chemotherapy side effects

Thank you for sending through information regarding this project. From the documents submitted it appears that the project has appropriate ethical clearance as well as support/engagement from the appropriate clinical lead. The protocol has been reviewed by the NNUH's Information Governance Manager and complies with Trust standards in this regard.

With these in place, there is no impediment to the project running at the NNUH. I think it is important that any results of the project should be reported back to the clinical teams involved for quality improvement purposes.

Yours sincerely

Stuart Williams MA MRCP FRCR
Consultant Radiologist
Trust Clinical Lead for Audit and Improvement

North West Anglia NHS Foundation Trust – Peterborough City Hospital and Hinchingbrooke Hospital

Reply Reply All Forward IM

Mon 28/01/2019 12:30

RDDepartment (NORTH WEST ANGLIA NHS FOUNDATION TRUST) <nwangliaft.rddepartment@nhs.net>

NIHR Portfolio Number: 40736. Acknowledgement of participation in service evaluation at North West Anglia NHS Foundation Trust

To Kumud Kantilal (PHA - Postgraduate Researcher)

Cc Pchhaemoncresearch (NORTH WEST ANGLIA NHS FOUNDATION TRUST); Hhhaemoncresearch (NORTH WEST ANGLIA NHS FOUNDATION TRUST)

You forwarded this message on 28/01/2019 13:20.
This message was sent with High importance.

Dear All,

RE: NIHR Portfolio Number: 40736 Acknowledgement of participation in service evaluation at North West Anglia NHS Foundation Trust

Full Project Title: Design and implementation of novel pharmacy service models for older cancer survivors: The Service Evaluation of Cancer Side Effect Support for Older People: CaSES

Ref: HP/2018/CaSES

This email acknowledges the participation of North West Anglia NHS Foundation Trust, Peterborough City Hospital and Hinchingbrooke Hospital sites in the above service evaluation.

We agree to start this service evaluation when you as sponsor give the green light to begin.

Sponsor responsibilities:

It is the sponsors' responsibility to ensure that the R&D department are made aware of the end of involvement for North West Anglia NHS Foundation Trust.

Ensure that recruitment figures are added to the National recording system.

Local Site responsibilities:

The NIHR Contract requires providers of NHS services to submit performance data on a 70-day benchmark to recruit first patients into projects.

It is your responsibility to upload recruitment figures onto the research governance software EDGE in a timely manner and respond to requests for report information in a timely manner. If any assistance or training in the use of EDGE is required please contact the R&D department (nwangliaft.rddepartment@nhs.net). This system will then be used to report on recruitment and the success of you reaching the 70-day recruitment benchmark and may influence any external funding you receive.

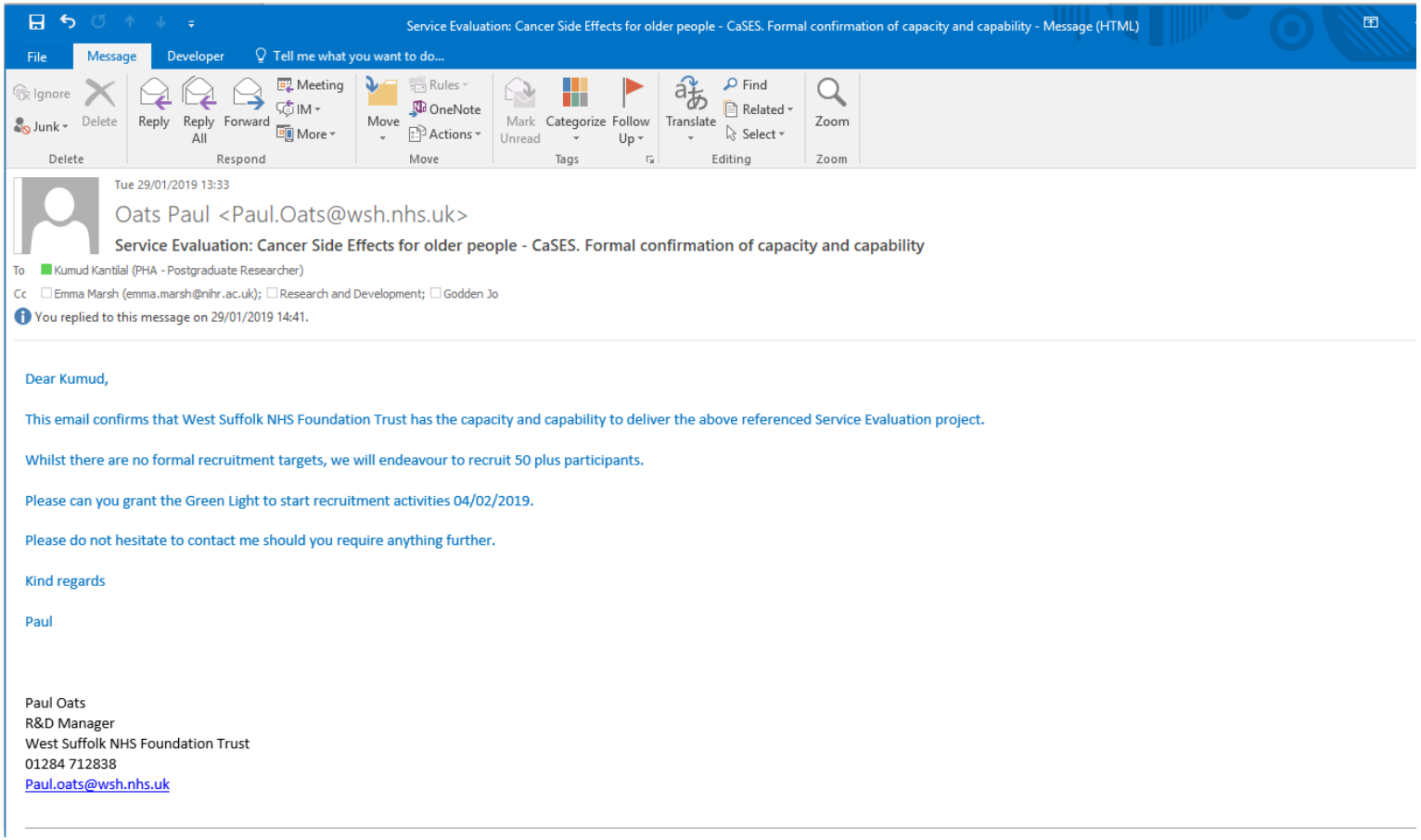
If you wish to discuss further, please do not hesitate to contact the team.

Kind regards

Hannah

North West Anglia NHS FT Hospitals Research and Development Department

West Suffolk NHS Foundation Trust



East Suffolk and North Essex NHS Foundation Trust – Colchester Hospital

19/005 - CaSES Study ***R&D Approval***

EA

Elden, Ashley <Ashley.Elden@ipswichhospital.nhs.uk>
To Kumud Kantilal (PHA - Postgraduate Researcher)
Cc Driscoll, Celine; 'Hayley.Hewer@colchesterhospital.nhs.uk'; 'LouiesAndrew.Mabelin@colchesterhospital.nhs.uk'; 'Nicola.Cutmore@colchesterhospital.nhs.uk'; 'Katrina.Cooke@colchesterhospital.nhs.uk'; 'Romuald.Lucek@colchesterhospital.nhs.uk'; 'Thorogood, Lucy'; 'R&D'

You replied to this message on 23/01/2019 15:15.

Dear Kumud

Name of study: **CaSES – Cancer Side Effect Support for Older People**
R&D number: **19/005**
IRAS number: **201819**
CPMS ID: **40736**
Sponsor: **University of East Anglia**
Funder: **Pharmacy Research UK / The Harold and Marjorie Moss Charitable Fund**

I am writing regarding the above project which has now been reviewed by the Research & Development team.

I am pleased to confirm that we are happy to give approval for this service evaluation to take place at East Suffolk and North Essex NHS Foundation Trust.
We will initially be recruiting patients at our Colchester Hospital site only but will consider recruiting patients at Ipswich Hospital if necessary.

Although this project has been classified as Service Evaluation rather than Clinical Research it will be overseen by the R&D team.

We have been assured by CRN: Eastern that as this project has been adopted onto the NIHR Portfolio we will receive an accrual for each participant that we recruit.
We will of course endeavour to recruit 50 participants by 31 March 2019 as requested. Please confirm that you would be happy for us to over-recruit if possible.

I understand that you are providing our research delivery team with a tablet for use in clinic (for patients to complete the survey). We will try and source some additional tablets internally, otherwise, we will use paper surveys and will upload the details to the study system in a timely manner.

The CRN: Eastern have advised that this Service Evaluation forms part of a larger research study. We would be very interested if sites are sought for the research aspect of the study.

Please confirm by reply that you are happy for us to begin identifying and approaching patients for this study, this will then be taken as our green light to start.

Many thanks and we look forward to hearing from you.

Best wishes

Ashley Elden
R&D Facilitator
Based at Ipswich Hospital - R&D Office (N043), Trust Research Unit
East Suffolk and North Essex NHS Foundation Trust, Heath Road, Ipswich IP4 5PD
Tel: 01473 704343 (ext 6343) ashley.elden@ipswichhospital.nhs.uk
: East Suffolk and North Essex NHS Foundation Trust - Research and Development

Ctrl+Click to follow link

Guy's and St Thomas' NHS Foundation Trust – Guy's Hospital site

RE: Service evaluation for review please - project 9327 - Cancer side effect support for older people (CaSES)

KK Kantilal Kumud <Kumud.Kantilal@gstt.nhs.uk>
To Maisey Nick
Cc Karapanagiotou Eleni; Kumud Kantilal (PHA - Postgraduate Researcher)

Reply | Reply All | Forward | ...
Fri 25/01/2019 16:56

From: Maisey Nick
Sent: 10 December 2018 11:57
To: Kantilal Kumud <Kumud.Kantilal@gstt.nhs.uk>
Subject: RE: Service evaluation for review please - project 9148 - Cancer side effect support for older people (CaSES)

Hi Kumud

Great to hear from you

Signed off

Thanks!

From: Kantilal Kumud
Sent: 07 December 2018 12:48
To: Maisey Nick <Nick.Maisey@gstt.nhs.uk>
Cc: Karapanagiotou Eleni <Eleni.Karapanagiotou@gstt.nhs.uk>; k.kantilal@uea.ac.uk
Subject: Service evaluation for review please - project 9148 - Cancer side effect support for older people (CaSES)

Dear Nick

I hope this email finds you well.

I used to work in oncology pharmacy, until 2016. I am currently doing a PhD at the University of East Anglia. Lena Karapanagiotou is part of my supervisory team.

We are planning to survey patients at Guy's Cancer Centre to evaluate the impact of anticancer treatment side effects on older people living with and beyond cancer and the extent to which existing oncology services are supporting older cancer patients to manage their anticancer treatment side effects. We plan to survey patients with a breast, colorectal and prostate cancer diagnosis, age 65 and above.

I have submitted a service evaluation on the online clinical audit database for review. I have attached the protocol to the online application, which has been reviewed by Lena and Janine Mansi. I have also emailed the protocol to Paul Ross, Sarah Rudman and Ines Sandri. The protocol has been reviewed by the ethics department at the University of East Anglia (School of Medicine and Health Science).

I would like to start surveying patients at Guy's in January.

Please get back to me if you have any queries.

Thank you,
Kumud
Postgraduate Researcher

Appendix C. Online questionnaire and questionnaire psychometric properties for Chapter 3

University of East Anglia

Cancer side effect support for older people - CaSES

Cancer Side Effect Support for Older People - CaSES survey

Together with staff at the hospital, we are interested in finding out how things are for you in relation to anticancer treatment side effects. We also want to know about your experience of how well we are doing in the cancer clinic to help you manage side effects of anticancer treatment and make improvements based on your feedback.

Participation in this survey is voluntary.

By completing the survey, I state that:

- I understand the purpose of the study and what I will be asked to do.
- I have been able to discuss my involvement in the study with the survey administrators (people handing out the survey) if I wished to do so.
- The survey administrators have answered any questions that I had about the study and I am happy with the answers.

- I understand that being in this study is completely voluntary and I do not have to take part. My decision whether to be in the study will not affect my current care or relationship with the health care professionals at the hospital and the survey administrators or anyone else at the University of East Anglia now or in the future.
- I understand that if I decide to take part in the study and then change my mind, I am free to withdraw at any time before I have completed answering the survey. Once I have completed the questions, my responses cannot be withdrawn because they are anonymous and therefore the survey administrators will not be able to tell which one is mine.
- I understand that personal information about me that is collected over the course of this survey will be stored securely and will only be used for purposes that I have agreed to. I understand that information about me will only be told to others with my permission, except as required by law.
- I understand that the results of this survey may be published, and that publications will not contain my name or any identifiable information about me.

The information that you give us will be kept anonymous. We will not pass the information on to the healthcare team at the hospital. This means you do not have to write your name on the questionnaire, and that all information will be treated confidentially.

Please read each question carefully. There are no right or wrong answers to these questions. You may find some of the questions feel rather personal. However, it is important we ask about these issues so that we can understand what kind of care you need. If you decide there are any questions you would rather not answer please just go to the next question.

The CaSES survey is led by the Schools of Pharmacy and Health Sciences, University of East Anglia. Our team is working with healthcare professionals and patient representatives at Norfolk and Norwich University Hospital and Guy's Cancer Centre. We are responsible for the survey design, conduct, data analysis and interpretation and dissemination of results.

If you have any comments or questions about the survey please feel free to contact **Kumud Kantilal (01603-591973).**

Participant eligibility check - for office use only

Survey administrator to complete the following information before proceeding to the survey questions.

Site name:

Participant number:

Participant age (years):

Participant sex:

- Male
- Female

Partcipant cancer type:

- Breast

- Bowel
- Prostate

Consent statement

I agree to completing this survey

- ○ Yes
- ○ No

Section A: Your experience of anticancer treatment side effects and support from cancer services

This survey is about your experience of anticancer treatment and the support you get to manage any problems. Anticancer treatment includes medicines used to destroy cancer cells or affect the way they grow and divide. These medicines could be given to you in the hospital or used at home, such as injections, tablets or capsules.

We want to know whether you are getting the support you need from us to manage any problems with your anticancer treatment.

When we use the words ‘us’ or ‘staff’ we mean all the staff in the hospital or anyone or services they may have referred you to.

What you tell us will help us find out whether we need to change what we are doing.

In this section we want you to think about any side effects that you think have been caused by your anticancer treatment. We also want to know how supported you felt to manage these side effects.

Over the last MONTH have you had any side effects that you think are caused by your anticancer treatment? * *Required*

- ○ Yes
- ○ No

If yes, please describe your experience

In the next section we want you to think about side effects you think have been caused by your anticancer treatment. We also want to know how supported you felt to mange these side effects.

In the last MONTH, how much have your anticancer treatment side effects affected your **physical health?** *(e.g. urinary, bowel or fatigue problems, feeling or being sick)*

- Never
- Rarely
- Sometimes
- Often
- Always

What do you think about this statement: **The staff have supported me with managing these physical problems.**

- ○ Strongly agree
- ○ Agree
- ○ Neither
- ○ Disagree
- ○ Strongly disagree

In the last MONTH, how much have your anticancer treatment side effects affected your **emotional well-being?** *(e.g. anxiety, fear, worry, anger, depression, coming to terms with thinking of yourself in a different way)*

- ○ Never
- ○ Rarely
- ○ Sometimes
- ○ Often
- ○ Always

What do do think about this statement: **The staff have supported me with managing these emotional / psychological problems.**

- Strongly agree
- Agree
- Neither
- Disagree
- Strongly disagree

In the last MONTH, how much have your anticancer treatment side effects affected your **social life?** *(e.g.return to work, benefits, insurance, returning to your normal activities)*

- Never
- Rarely
- Sometimes
- Often
- Always

What do you think about this statement: **The staff have supported me with managing these social problems.**

- Strongly agree
- Agree
- Neither
- Disagree
- Strongly disagree

In the last MONTH, how much have your anticancer treatment side effects affected your **relationships with family and friends?** *(e.g. family arguments, difficulty in talking about relationships, intimacy issues, lack of interest in sex, feeling unloved or unlovable)*

- Never
- Rarely
- Sometimes
- Often
- Strongly disagree

What do you think about this statement: **The staff have supported me with managing relationship problems with family and friends.**

- Strongly agree
- Agree
- Neither
- Disagree
- Strongly disagree

In the last MONTH, how much have your anticancer treatment side effects affected **your ability to deal with problems** related to cancer or anticancer treatment?

- Never
- Rarely
- Sometimes
- Often
- Always

What do you think about this statement: **The staff have helped me to deal with any problems related to cancer or anticancer treatment.**

- ○ Strongly agree
- ○ Agree
- ○ Neither
- ○ Disagree
- ○ Strongly disagree

In the last MONTH, how much have your anticancer treatment side effects affected your ability to **manage other long-term conditions?** *(e.g. high blood pressure, diabetes, heart problems, arthritis, etc.)*

- ○ Never
- ○ Rarely
- ○ Sometimes
- ○ Often
- ○ Always

What do you think about this statement: **The staff have supported me with managing other long-term conditions.**

- Strongly agree
- Agree
- Neither
- Disagree
- Strongly disagree

In the last MONTH, how much have your anticancer treatment side effects affected your ability to **adjust to life after cancer treatment?** *(e.g. returning to your daily routine and usual activities)*

- Never
- Rarely
- Sometimes
- Often
- Always

What do you think about this statement: **The staff have supported me with adjusting to life after cancer treatment.**

- Strongly agree
- Agree
- Neither
- Disagree
- Strongly disagree

Overall, how satisfied are you with the general support and care you received **during** your anticancer treatment?

- ○ Very dissatisfied
- ○ Dissatisfied
- ○ Neither
- ○ Satisfied
- ○ Very satisfied

Overall, how satisfied are you with the general support and care you received **after completing** your anticancer treatment?

- ○ Very dissatisfied
- ○ Dissatisfied
- ○ Neither
- ○ Satisfied
- ○ Very satisfied
- ○ I have not yet completed my anticancer treatment

Section B: Getting information and support for anticancer therapy side effects

In this section, we want you to think about where you get information and support to manage side effects related to anticancer treatment.

When you get any side effects from anticancer treatment, who do you turn to or where do you go for information and support to manage them?

- ☐ Your oncologist (hospital cancer doctor)
- ☐ Your clinical nurse specialist (CNS - hospital cancer nurse)
- ☐ Your hospital nurse (nurse in the cancer outpatient department, chemotherapy/cancer day unit, Acute Oncology Service (AOS))
- ☐ Your GP
- ☐ Your practice nurse (nurse in the GP surgery)
- ☐ Your friends
- ☐ Your family
- ☐ The internet (e.g. Macmillan website, Big C website, Hospital website, Cancer Research UK website)
- ☐ Other professional(s) e.g. pharmacists, physiotherapists, psychologists, complementary therapists

If you selected Other professional(s), please tell us who this is.

Was there ever a time when you did not contact anyone or seek out information when you had side effects from anticancer treatment?

- ○ Yes
- ○ No

Please tell us why you did not contact anyone or seek out support.

- ○ I did not need any support or information
- ○ I did not know who to ask
- ○ I did not know where to look for information
- ○ I did not want to bother the staff
- ○ Other

If you selected Other, please specify:

Section C: Your overall wellbeing

This section is about your wellbeing and how you felt over the past week.

How would you rate your overall wellbeing over the past week?

	1	2	3	4	5	
As good as it can be	☐	☐	☐	☐	☐	As bad as it can be

Section D: Other comments

We would like to know what we are doing well and how we can improve the service that we are providing. We will remove any information that could identify you.

Is there anything that we can improve to better support you in managing the side effects of anticancer treatment?

Is there anything particularly good about the support you have had to manage side effects of anticancer treatment?

Any other comments?

Section E: About you

This section is about your background. This information will help us analyse and organise your results.

Which statement best describes your living arrangements?

- I live with my partner/spouse/family/friends
- I live alone
- I live in a nursing home, hospital or other long term care home
- Other

If you selected Other, please specify:

Do you have health condition(s), other than cancer?

- Don't know
- No
- Yes

If you selected Yes, please list these health conditions:

Thank you

Thank you for taking the time to complete this survey.

Psychometric properties of the measure used in Chapter 3

Table C1: Response distribution for participants experiencing side effects related to anticancer treatment (N=343)

Side effects caused by anticancer treatment	N (%)
No	173 (50.4)
Yes	170 (49.6)

Table C2: Scores for anticancer treatment related negative consequences (N=170)

Domain	Median score (IQR)	n (%)					
		Never Score 0	Rarely Score 1	Sometimes Score 2	Often Score 3	Always Score 4	Missing
Physical health	2 (1, 3)	31 (18.2)	18 (10.6)	56 (32.9)	35 (20.6)	29 (17.1)	1 (0.6)
Emotional wellbeing	2 (0, 2)	52 (30.6)	30 (17.6)	60 (35.3)	20 (11.8)	6 (3.5)	2 (1.2)
Social life	0 (0, 2)	84 (49.4)	18 (10.6)	37 (21.8)	19 (11.2)	8 (4.7)	4 (2.3)
Relationships	0 (0, 2)	114 (67)	17 (10)	27 (15.9)	7 (4.1)	2 (1.2)	3 (1.8)
Ability to deal with cancer or anticancer treatment related problems	0 (0, 1)	108 (63.5)	19 (11.2)	28 (16.5)	6 (3.5)	4 (2.3)	5 (3)
Ability to manage other long-term conditions	0 (0, 1)	125 (73.6)	10 (5.9)	23 (13.6)	4 (2.3)	4 (2.3)	4 (2.3)
Ability to adjust to life after cancer	0 (0, 2)	99 (58.2)	19 (11.2)	25 (14.7)	11 (6.5)	7 (4.1)	9 (5.3)

Table C3: Scores for staff support to manage anticancer treatment related negative consequences (N=170)

Domain (n)	Median score (IQR)	n (%)					
		Strongly Agree Score 1	Agree Score 2	Neither Score 3	Disagree Score 4	Strongly Disagree Score 5	Missing
Physical health (139)	2 (1.3)	40 (28.9)	43 (30.9)	37 (26.6)	7 (5)	2 (1.4)	10 (7.2)
Emotional wellbeing (118)	2 (2,3)	25 (21.2)	30 (25.4)	46 (39)	6 (5.1)	3 (2.5)	8 (6.8)
Social life (86)	3 (2,3)	7 (8.1)	15 (17.4)	52 (60.5)	4 (4.7)	2 (2.3)	6 (7)
Relationships (56)	3 (2,3)	5 (8.9)	9 (16)	31 (55.4)	3 (5.4)	2 (3.6)	6 (10.7)
Ability to deal with cancer or anticancer treatment related problems (62)	2 (1,3)	22 (35.5)	13 (21)	18 (29)	2 (3.2)	1 (1.6)	6 (9.7)
Ability to manage other long-term conditions (45)	3 (1,3)	9 (20)	7 (15.6)	20 (44.4)	0	3 (6.7)	6 (13.3)
Ability to adjust to life after cancer (71)	3 (1,3)	16 (22.5)	13 (18.3)	27 (38.1)	5 (7)	1 (1.4)	9 (12.7)

Table C4: Scores for satisfaction with general support and care to manage anticancer treatment related negative consequences (N=170)

	n (%)						
	Very Satisfied Score 1	Satisfied Score 2	Neither Score 3	Dissatisfied Score 4	Very Dissatisfied Score 5	Treatment not completed	Missing
During treatment	114 (67.1)	39 (22.9)	8 (4.7)	1 (0.6)	8 (4.7)	N/A	0
After completing treatment	34 (20)	18 (10.6)	4 (2.3)	4 (2.3)	1 (0.6)	106 (62.4)	3 (1.8)

Table C5: Overall wellbeing scores (N=343)

	n (%)					
	As good as it can be Score 1	Good Score 2	Neither Score 3	Bad Score 4	As bad as it can be Score 5	Missing
Overall wellbeing	155 (45.2)	91 (26.5)	59 (17.2)	24 (7)	5 (1.5)	9 (2.6)

Figure C1: Response distribution of the negative impact of anticancer treatment (floor effects)

Scores: 0=Never, 1=Rarely, 2=Sometimes, 3=Often, 4=Always

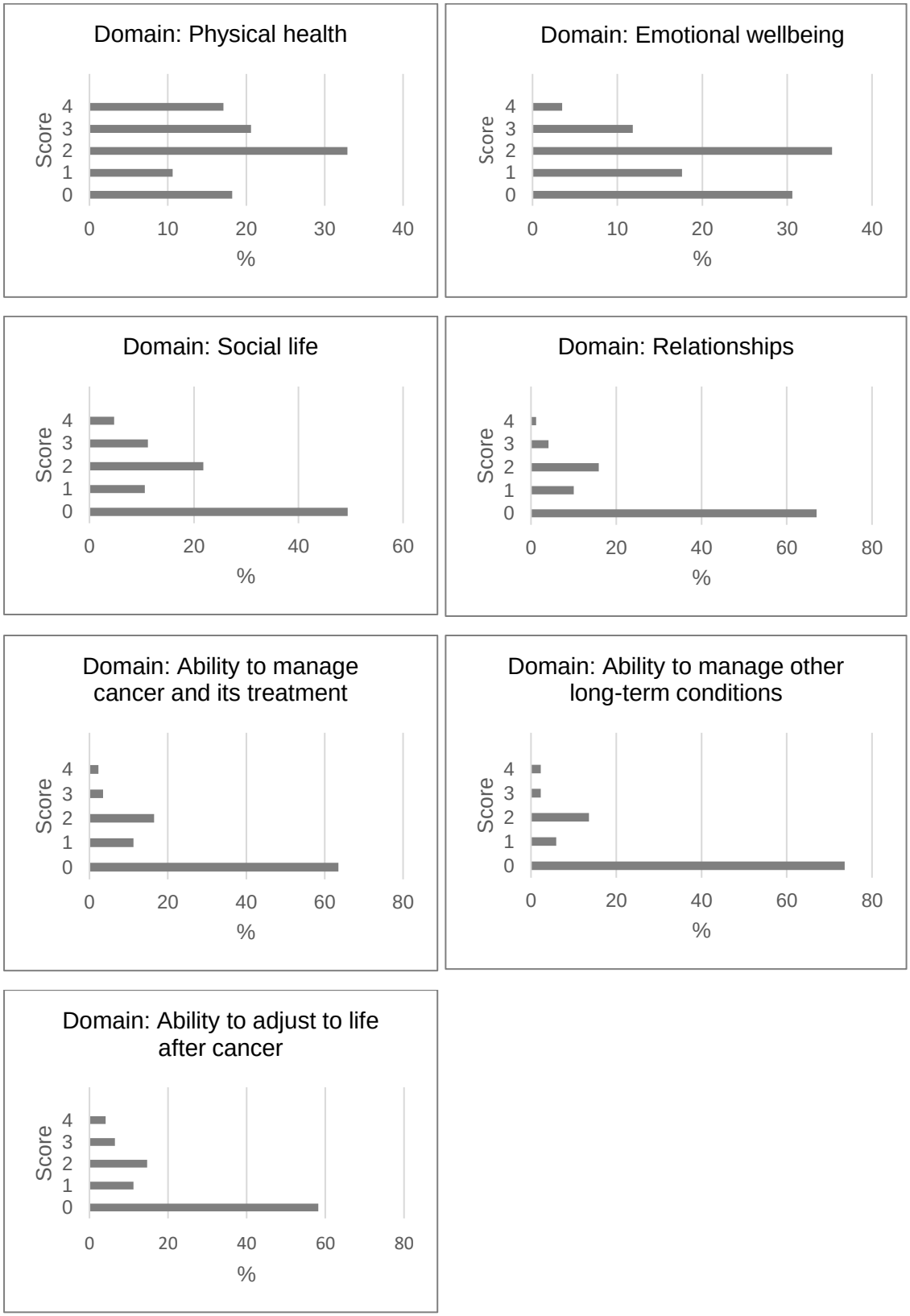


Figure C2: Response distribution of the staff support to manage anticancer treatment related negative consequences (floor effects)

Scores: 1=Strongly Agree, 2=Agree, 3=Neither agree nor disagree, 4=Disagree, 5=Strongly Disagree

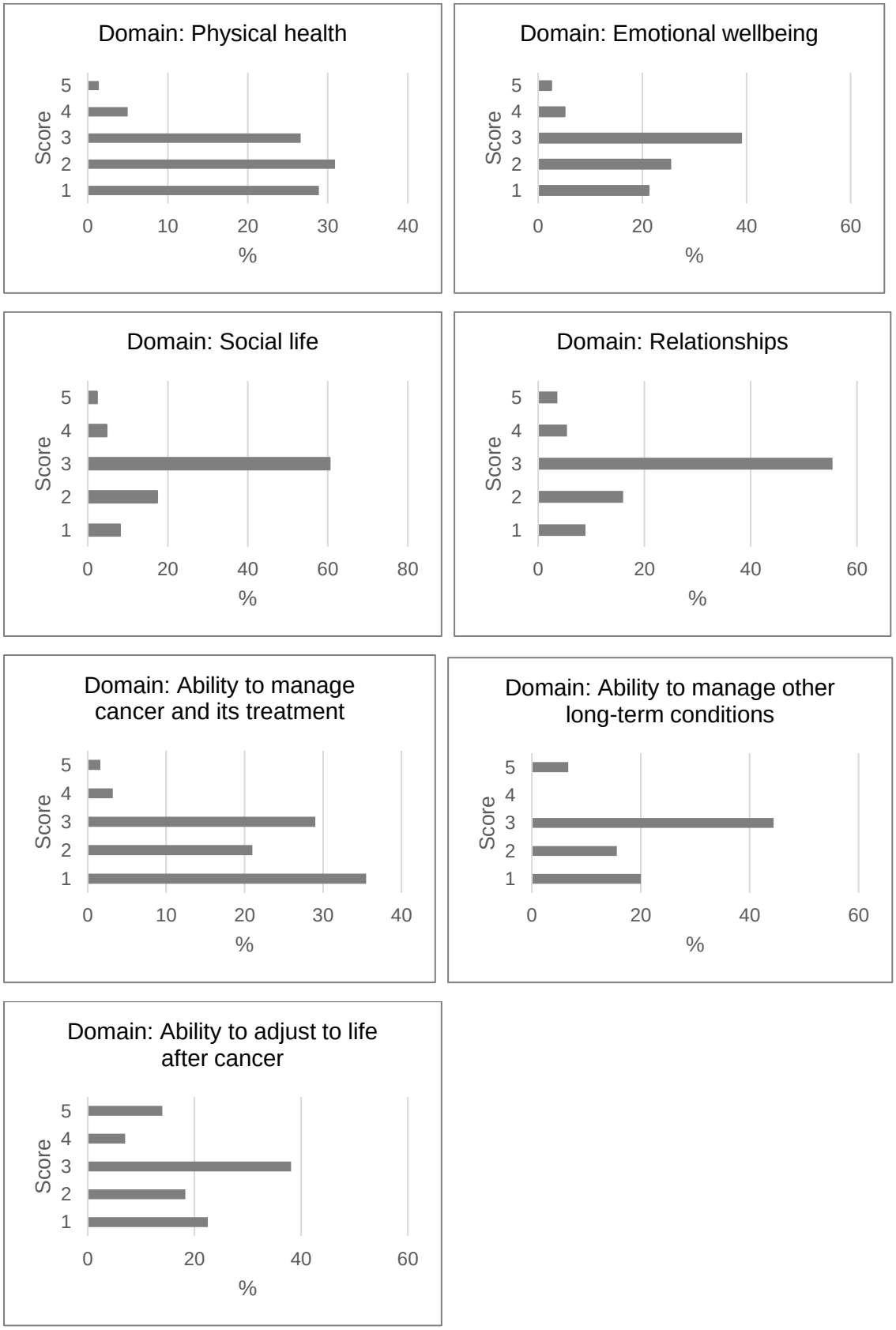


Figure C3: Response distribution of the satisfaction with general support and care to manage anticancer treatment related negative consequences (floor effects)

Scores: 1=Very Satisfied, 2=Satisfied, 3=Neither satisfied nor dissatisfied, 4=Dissatisfied, 5=Very Dissatisfied

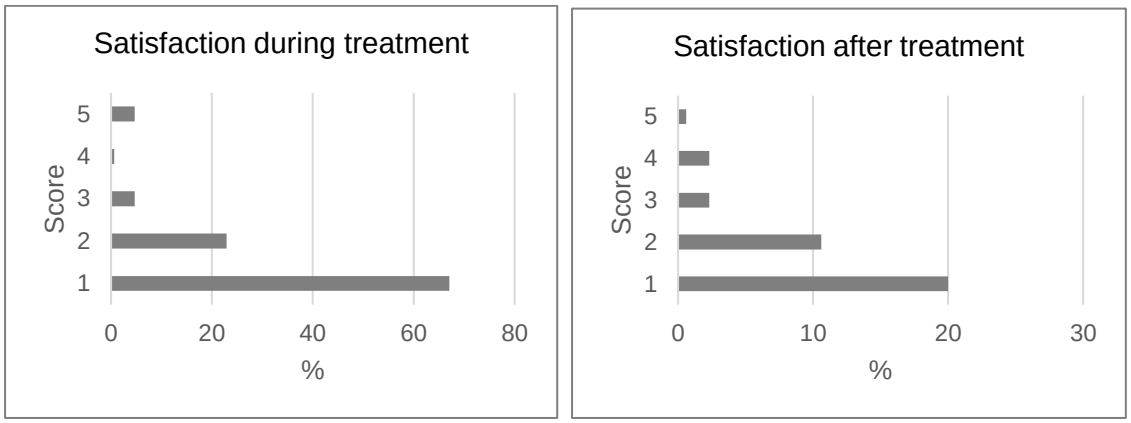


Figure C4: Response distribution of the satisfaction with general support and care to manage anticancer treatment related negative consequences (floor effects)

Scores: 1=As good as it can be, 2=Good, 3=Neither good nor bad, 4=Bad, 5=As bad as it can be

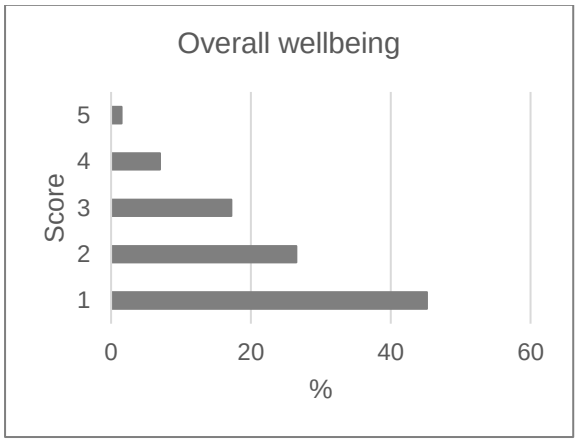


Table C6: Scores for anticancer treatment related negative consequences for participants completing primary treatment up to 2 years ago (n=73)

Domain	Median score (IQR)	n (%)					
		Never Score 0	Rarely Score 1	Sometimes Score 2	Often Score 3	Always Score 4	Missing
Physical health	2 (1, 3)	7 (9.6)	6 (8.2)	17 (23.3)	6 (8.2)	8 (11)	29 (39.7)
Emotional wellbeing	1 (0, 2)	13 (17.8)	11 (15.1)	18 (24.7)	2 (2.7)	0	29 (39.7)
Social life	0 (0, 2)	23 (31.5)	6 (8.2)	8 (11)	6 (8.2)	1 (1.4)	29 (39.7)
Relationships	0 (0, 0)	34 (46.6)	4 (5.5)	5 (6.8)	1 (1.4)	0	29 (39.7)
Ability to deal with cancer or anticancer treatment related problems	0 (0, 1)	30 (41.1)	5 (6.8)	6 (8.2)	1 (1.4)	2 (2.7)	29 (39.7)
Ability to manage other long-term conditions	0 (0, 0)	37 (50.7)	2 (2.7)	3 (4.1)	1 (1.4)	1 (1.4)	29 (39.7)
Ability to adjust to life after cancer	0 (0, 1)	24 (32.9)	9 (12.3)	5 (6.8)	2 (2.7)	2 (2.7)	31 (42.5)

Table C7: Scores for anticancer treatment related negative consequences for participants completing primary treatment more than 2 years ago (n=29)

Domain	Median score (IQR)	n (%)					
		Never Score 0	Rarely Score 1	Sometimes Score 2	Often Score 3	Always Score 4	Missing
Physical health	3 (2, 3)	0	2 (6.9)	3 (10.3)	4 (13.8)	3 (10.3)	17 (58.6)
Emotional wellbeing	2 (1, 3)	2 (6.9)	3 (10.3)	3 (10.3)	1 (3.4)	3 (10.3)	17 (58.6)
Social life	1 (0, 3)	5 (17.2)	1 (3.4)	2 (6.9)	2 (6.9)	2 (6.9)	17 (58.6)
Relationships	0 (0, 2)	7 (24.1)	1 (3.4)	1 (3.4)	1 (3.4)	2 (6.9)	17 (58.6)
Ability to deal with cancer or anticancer treatment related problems	0 (0, 1)	8 (27.6)	2 (6.9)	0	1 (3.4)	1 (3.4)	17 (58.6)
Ability to manage other long-term conditions	0 (0, 0)	9 (31)	1 (3.4)	1 (3.4)	1 (3.4)	0	17 (58.6)
Ability to adjust to life after cancer	0 (0, 3)	7 (24.1)		1 (3.4)	1 (3.4)	3 (10.3)	17 (58.6)

Table C8: Median scores (interquartile range) for anticancer treatment related negative consequences

Domain	Participants experiencing anticancer treatment related negative consequences					
	Participants who completed primary anticancer treatment up to 2 years ago		Participants who completed primary anticancer treatment > 2 years ago		Mann-Whitney U	p
	n	Median (IQR)	n	Median (IQR)		
Physical health	44	2 (1, 3)	12	3 (2, 3)	191.5	0.135
Emotional wellbeing	44	1 (0, 2)	12	2 (1, 3)	185.5	0.101
Social life	44	0 (0, 2)	12	1 (0, 3)	211.5	0.260
Relationships	44	0 (0, 0)	12	0 (0, 2)	201	0.106
Ability to deal with cancer or anticancer treatment related problems	44	0 (0, 1)	12	0 (0, 1)	258.5	0.894
Ability to manage other long-term conditions	44	0 (0, 0)	12	0 (0, 0)	240.5	0.482
Ability to adjust to life after cancer	42	0 (0, 1)	12	0 (0, 3)	222.5	0.494

Appendix D. Ethical approval letter for Chapter 4

Faculty of Medicine and Health Sciences Research Ethics Committee

Kumud Kantilal
PHA

Research & Innovation Services
Floor 1, The Registry
University of East Anglia
Norwich Research Park
Norwich, NR4 7TJ

Email: fmh.ethics@uea.ac.uk

Web: www.uea.ac.uk/researchandenterprise

07 June 2019

Dear Kumud

Project title: Supporting self-management in older cancer survivors: a realist review

Reference: 201819 - 124

I have considered your proposal to conduct a realist review and I confirm that your proposal has been approved.

Please could you ensure that any further amendments to either the protocol or documents submitted are notified to us in advance and also that any adverse events which occur during your project are reported to the Committee. Please could you also arrange to send us a report once your project is completed.

Approval by the FMH Research Committee should not be taken as evidence that your study is compliant with GDPR and the Data Protection Act 2018. If you need guidance on how to make your study GDPR compliant, please contact your institution's Data Protection Officer.

Yours sincerely

Prof Alastair Forbes
Chair
FMH Research Ethics Committee

CC **Debi Bhattacharya**
Maya Kumar (R206051)

Appendix E. Realist and Meta-narrative Evidence Syntheses: Evolving Standards (RAMESES) publication standards checklist for Chapter 4

RAMESES* publication standards: realist syntheses * Realist And MEta-narrative Evidence Syntheses: Evolving Standards					
No.	**SECTION / Topic**	**Checklist item**	**Reported**		**Comments**
			Yes	**N/A**	
TITLE					
1		In the title, identify the document as a realist synthesis or review	☒	☐	
ABSTRACT					
2		While acknowledging publication requirements and house style, abstracts should ideally contain brief details of: the study's background, review question or objectives; search strategy; methods of selection, appraisal, analysis and synthesis of sources; main results; and implications for practice.	☒	☐	
INTRODUCTION					
3	Rationale for review	Explain why the review is needed and what it is likely to contribute to existing understanding of the topic area.	☒	☐	
4	Objectives and focus of review	State the objective(s) of the review and/or the review question(s). Define and provide a rationale for the focus of the review.	☒	☐	
METHODS					
5	Changes in the review process	Any changes made to the review process that was initially planned should be briefly described and justified.	☐	☒	No changes were made to the protocol.
6	Rationale for using realist synthesis	Explain why realist synthesis was considered the most appropriate method to use.	☒	☐	

7	Scoping the literature	Describe and justify the initial process of exploratory scoping of the literature.	☒	☐	
8	Searching processes	While considering specific requirements of the journal or other publication outlet, state and provide a rationale for how the iterative searching was done. Provide details on all the sources accessed for information in the review. Where searching in electronic databases has taken place, the details should include, for example, name of database, search terms, dates of coverage and date last searched. If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified and selected.	☒	☐	
9	Selection and appraisal of documents	Explain how judgements were made about including and excluding data from documents and justify these.	☒	☐	
10	Data extraction	Describe and explain which data or information were extracted from the included documents and justify this selection.	☒	☐	
11	Analysis and synthesis processes	Describe the analysis and synthesis processes in detail. This section should include information on the constructs analysed and describe the analytic process.	☒	☐	
RESULTS					
12	Document flow diagram	Provide details on the number of documents assessed for eligibility and included in the review with reasons for exclusion at each stage as well as an indication of their source of origin (for example, from searching databases, reference lists and so on). You may consider using the example templates (which are likely to need modification to suit the data) that are provided.	☒	☐	A PRISMA Flow Diagram has been included.

13	Document characteristics	Provide information on the characteristics of the documents included in the review.	☒	☐	
14	Main findings	Present the key findings with a specific focus on theory building and testing.	☒	☐	
DISCUSSION					
15	Summary of findings	Summarize the main findings, taking into account the review's objective(s), research question(s), focus and intended audience(s).	☒	☐	
16	Strengths, limitations and future research directions	Discuss both the strengths of the review and its limitations. These should include (but need not be restricted to) (a) consideration of all the steps in the review process and (b) comment on the overall strength of evidence supporting the explanatory insights which emerged. The limitations identified may point to areas where further work is needed.	☒	☐	
17	Comparison with existing literature	Where applicable, compare and contrast the review's findings with the existing literature (for example, other reviews) on the same topic.	☒	☐	
18	Conclusion and recommendations	List the main implications of the findings and place these in the context of other relevant literature. If appropriate, offer recommendations for policy and practice.	☒	☐	
19	Funding	Provide details of funding source (if any) for the review, the role played by the funder (if any) and any conflicts of interests of the reviewers.	☒	☐	

Appendix F. Online survey administered prior to stakeholder workshops to support programme theory prioritisations for Chapter 4

Designing services for older people living with and beyond cancer

Development of initial programme theories.

We would be grateful if you could indicate whether you feel that the following statements are important, not important or if you are unsure.

The questions relate to how practitioners, such as doctors, nurses, pharmacists, dieticians, etc. can help people to help themselves - this is called self-management.

In this survey when we say self-management support (SMS), we mean where practitioners encourage and support people living with and beyond cancer to improve or maintain their health and well-being. Some examples of this include how to take medication, monitoring symptoms such as pain, tiredness or low mood, making sure you understand information and making the most of encounters with practitioners.

Your responses are anonymous and there are no right or wrong answers.

1. Practitioners will be effective in supporting patients to self-manage if the practitioner has the required knowledge about the cancer pathway.

- ◯ Important
- ◯ Not sure
- ◯ Not important

2. Practitioners will correctly identify and signpost patients to self-manage if the practitioner has the required knowledge about the consequences of cancer treatment.

- ◯ Important
- ◯ Not sure
- ◯ Not important

3. Practitioners are more likely to initiate discussions regarding self-management with patients and carers if they feel equipped to conduct consultations with patients and carers experiencing emotional distress.

- ◯ Important
- ◯ Not sure
- ◯ Not important

4. Practitioners are more likely to initiate discussions regarding self-management with patients and carers if they feel that it is a part of their role.

- ◯ Important
- ◯ Not sure
- ◯ Not important

5. Practitioners are more likely to initiate discussions regarding self-management with patients and carers if they feel that this role is endorsed by colleagues from other professions.

- ◯ Important
- ◯ Not sure
- ◯ Not important

6. Self-management support is more likely to be successful if the primary care team are united in their vision of how it should achieved.

- ◯ Important
- ◯ Not sure
- ◯ Not important

7. If a practitioner is confident that they have the required knowledge and skills, then they are more likely to engage patients and carers in discussions about self-management support.

- ◯ Important
- ◯ Not sure
- ◯ Not important

8. If a practitioner feels that signposting patients to self-manage can be integrated into their current role, they are more likely to try doing it.

- ◯ Important
- ◯ Not sure
- ◯ Not important

9. If a practitioner believes that the self-management package is safe, then they will be more likely to encourage patients to engage with it.

- ◯ Important
- ◯ Not sure
- ◯ Not important

10. If a practitioner believes that supporting self-management will improve relationships with their patients, then they will be more likely to encourage patients to engage with it.

- ◯ Important
- ◯ Not sure
- ◯ Not important

11. If practitioners believe that initiating discussions about self-management will be time consuming, then they will be less likely to engage patients in discussion.

- ◯ Important
- ◯ Not sure
- ◯ Not important

12. If organisations provide rewards or sanctions dependent upon whether practitioners perform/do not perform SMS, then practitioners are more likely to undertake signposting to SMS.

- ◯ Important
- ◯ Not sure
- ◯ Not important

13. If organisations work with practitioners to integrate self-management into routine practice, then practitioners are more likely to engage with it.

- ◯ Important
- ◯ Not sure
- ◯ Not important

14. If the organisation demonstrates an expectation that supporting patients to self-manage is a part of the practitioner's role, then they are more likely to engage.

- ◯ Important
- ◯ Not sure
- ◯ Not important

15. If systems are organised to encourage and prioritise SMS then this will more likely lead to practitioners feeling supported (and equipped) to engage in SMS, resulting in SMS becoming part of the culture of care.

- ◯ Important
- ◯ Not sure
- ◯ Not important

16. If organisations work with practitioners to integrate a prompt for SMS into routine practice, then practitioners are more likely to remember to broach the topic of SMS.

- ◯ Important
- ◯ Not sure
- ◯ Not important

17. Additional funding is required to enable capacity to be built into the team for practitioners to deliver this new role of supporting SMS.

- ◯ Important
- ◯ Not sure
- ◯ Not important

18. Practitioners are more likely to initiate discussions regarding self-management with patients and carers if there are role models demonstrating that it can be done.

- ◯ Important
- ◯ Not sure
- ◯ Not important

19. If systems are organised to encourage SMS then SMS is more likely to become part of the culture of care.

- ◯ Important
- ◯ Not sure
- ◯ Not important

20. If organisations and practitioners feel that the concept of SMS is supported by patients and carers, then they are more likely to engage with implementing a SMS programme.

- ◯ Important
- ◯ Not sure
- ◯ Not important

21. Decision tools such as a traffic light system for when patients should seek hospital advice will reduce anxiety for practitioners arising from the fear that an emergency situation may be missed.

- ◯ Important
- ◯ Not sure
- ◯ Not important

22. If organisations routinely monitor and feedback on practitioner engagement with SMS, then they are more likely to initiate and maintain support of an SMS programme.

- ◯ Important
- ◯ Not sure
- ◯ Not important

23. If you have any comments or if you think that there is something we have missed, please add it here:

Enter your answer

Submit

Appendix G. Example Medline search for Chapter 4

Ovid MEDLINE(R) 1946 to August 30, 2019

Search run on 3Sep2019

#	Searches	Results	Type
1	neoplasm*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	2711445	Advanced
2	oncolo*.mp.	155531	Advanced
3	cancer*.mp.	1695939	Advanced
4	or/1-3	3222195	Advanced
5	nurse*.mp.	345740	Advanced
6	doctor*.mp.	121625	Advanced
7	pharmac*.mp.	3776848	Advanced
8	physician*.mp.	544010	Advanced
9	or/5-8	4653908	Advanced
10	self-management.mp.	17654	Advanced
11	self manag*.mp.	18638	Advanced
12	self care.mp.	41827	Advanced
13	self administ*.mp.	46509	Advanced
14	self medicat*.mp.	7290	Advanced
15	self efficacy.mp.	33173	Advanced
16	self monitor*.mp.	12263	Advanced
17	self guid*.mp.	674	Advanced
18	self regulat*.mp.	11491	Advanced
19	self direct*.mp.	5188	Advanced
20	self determin*.mp.	5086	Advanced
21	((patient? or client?) adj2 participat*).mp.	42236	Advanced
22	((patient? or client?) adj2 empower*).mp.	3215	Advanced
23	((patient? or client?) adj2 activat*).mp.	6279	Advanced
24	((patient? or client?) adj2 engag*).mp.	7132	Advanced
25	((patient? or client?) adj2 adjust*).mp.	10513	Advanced
26	((patient? or client?) adj2 accept*).mp.	56047	Advanced
27	or/10-26	274308	Advanced
28	implement*.mp.	449152	Advanced
29	deliver*.mp.	729574	Advanced
30	develop*.mp.	4632895	Advanced
31	improve*.mp.	2148475	Advanced
32	plan*.mp.	1577124	Advanced
33	guid*.mp.	829435	Advanced
34	policy.mp.	262734	Advanced
35	innovat*.mp.	153453	Advanced

36	disseminat*.mp.	140315	Advanced
37	(behavio?r adj2 chang*).mp.	25674	Advanced
38	adoption*.mp.	47998	Advanced
39	enabling.mp.	71478	Advanced
40	or/28-39	8615820	Advanced
41	4 and 9 and 27 and 40	3981	Advanced
42	limit 41 to "all adult (19 plus years)"	2348	Advanced
43	barrier*.mp.	285818	Advanced
44	facilitat*.mp.	495272	Advanced
45	43 or 44	756770	Advanced
46	42 and 45	480	Advanced
47	limit 46 to english language	471	Advanced
48	survivor*.mp.	104851	Advanced
49	47 and 48	36	Advanced
50	limit 47 to "all child (0 to 18 years)"	57	Advanced
51	47 not 50	414	Advanced

Appendix H. Online practitioner survey of unpublished self-management support interventions for Chapter 4

Healthcare professionals supporting self-management in cancer survivors

* Are you involved in designing or delivering a service to support self-management? *

* Have you had challenges or successes with designing or delivering your service? *

* We want to learn from your experiences *

~~~~~~

If you have experience of supporting cancer survivors to self-manage the long-term problems of cancer treatment, we would like to know the details of any local and regional projects that you were involved with.

We are interested in projects for people who have completed cancer treatment and are in the follow-up stage of the cancer journey.

Information about your challenges are just as important to us as your successes.

This survey is part of a larger study to Design Services for Cancer in Older people (DiSCO). We will combine your information with the literature and feedback from stakeholders to develop a specification for a community-based service to support cancer survivors to self-manage long-term problems from cancer treatment.

The survey is led by the University of East Anglia. Our team are responsible for the survey design, conduct, data analysis and interpretation and dissemination of results.

~~~~~~

* Required

Please read the information below before deciding to take part in the survey.

Is the information I give confidential?
Yes, your information will remain strictly confidential. Your answers will only be used for the purposes of this study.

How will we use information about you?
We will use your name, role, where you work and email address. Only the research team will have access to this information so that we can contact you, if you agree. We will keep all information safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.

What are your choices about how your information is used?
You are free to withdraw from the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the study to be reliable. This means that we won't be able to let you see or change that data we hold about you.

Where can you find out more about how your information is used?
You can find out more about how we use your information by sending an email to dataprotection@uea.ac.uk or k.kantilal@uea.ac.uk. Alternatively you can look at how we use your information from online surveys here: https://www.uea.ac.uk/about/legalstatements/data-protection-for-webforms

1. **What were you trying to achieve with your service?***E.g. We wanted to raise awareness of the importance of self-management and increase signposting in practitioners.* *

Enter your answer

2. **Who was involved in developing the service?***E.g. Doctors, nurses, pharmacists, commissioners, cancer patient groups, advocacy groups, charities.* *

Enter your answer

3. **Who was involved in delivering the service?***E.g. Practitioners such as nurses, pharmacists, or support staff such as healthcare assistants, social care staff.* *

Enter your answer

4. **Describe the role of the people involved in delivering the service?***E.g. The practice nurses were responsible for delivering a self-management education session.* *

Enter your answer

5. **Which patient groups were targeted for your service and why?***E.g. We developed a service for out-patients in a breast cancer follow-up clinic. A local survey showed that patients were not aware of the local services available to support them to maintain their physical and emotional wellbeing after completing cancer treatment.* *

Enter your answer

6. **What were the results? We are equally interested in projects that achieved AND those that did not achieve what you set out to do.***E.g. Despite identifying 29 patients across 4 GP surgeries who could benefit from our self-management education programme, only 10% of patients consented to attend the education session. Of those patients who consented to attend, 100% agreed to use the self-management care plan.* *

Enter your answer

7. **What do you think worked well and why? (We want to hear about aspects of the service which were effective, NOT final outcomes.)***E.g. We received positive feedback from the practitioners who attended the training session. I think they liked getting together and seeing that they were all experiencing the same challenges to supporting cancer survivors to self-manage the long term problems from cancer treatment. I also think that because we brought them out of their clinical environment they realised that we were serious about wanting to increase their knowledge and skills in survivorship care. They particularly liked the treatment guidelines we provided for them to use in practice.* *

Enter your answer

8. **What do you think didn't work well and why?***E.g. Not all community pharmacies signed up to the incentive scheme we developed. I think that they thought it wasn't achievable.* *

Enter your answer

9. **Any further comments***Please add any other information here that you think was key to delivering your service.* *

Enter your answer

10. **We would be grateful if you would be willing to share any documents related to your project such as a project report/evaluation and tools used in the project. Please confirm that you agree that we may contact you to request these documents.** *

- ◯ Yes - consent to contact by email
- ◯ No - no consent

11. **If you are happy for us to contact you, please provide us with your details in the boxes below.Your name:**

Enter your answer

12. **Your role**

Enter your answer

13. **Organisation name**

Enter your answer

14. **Your e-mail address**

Enter your answer

Submit

Appendix I. Illustrative quotes supporting development of the Context-Mechanism-Outcome configurations (CMOCs) showing barriers and enablers for facilitating delivery of self-management support by healthcare practitioners to adult cancer survivors for Chapter 4

Illustrative quotes for barriers to facilitating delivery of self-management support	Illustrative quotes for enablers for facilitating delivery of self-management support
CMOC1: Practitioners are equipped with the knowledge to enable them to support people to self-manage Programme theory: If practitioners have the knowledge to identify and manage treatment consequences and navigate the care pathway, including processes for escalating concerns (C), then they will engage in supporting patients to self-manage (O) because of increased practitioner confidence (M).	
On the health professional level, pain is not structurally and thoroughly discussed during consultations, due to a lack of time and knowledge. [p.2, Hochstenbach et al 2017] The majority of practitioners identified a training need around the knowledge of long-term health effects of cancer treatment. This was highest in the community nurses who expressed the greatest need for training… [p.90, Faithfull et al 2016] Differences were found between the professional groups in how confident they felt in managing consequences of cancer treatment and this was often related to the clinical practice they provided and increased when focused on specific client groups. [p.91, Faithfull et al 2016] Several providers mentioned being reluctant to raise sexual concerns without knowledge of available treatments, as one provider commented, "… I think part of it is [that] I don't want to ask a question that I don't have a solution for." [p.3203, Reese et al 2017]	Fundamental to the success of this [training] course was a clear expectation that the participating practice nurses would receive support from a nominated GP in their practice. [p.325, Campion-Smith 2014] Nurses both in hospital, community alongside allied health professionals saw training in survivorship as a priority [p.90, Faithfull et al 2016]
CMOC2: Practitioners have appropriate consultation skills to engage patients in discussions about self-management Programme theory: If practitioners have the necessary consultation skills (C), then they are more likely to engage patients in discussions about self-management where patients feel part of the decision-making process (O) because of mutual trust between practitioners and patients (M).	
Some providers worried that raising sexual concerns with patients who were uncomfortable could have detrimental effects on the patient-provider relationship [p.3202, Reese et al 2017] The strongest [patient communication] barriers tended to be negative beliefs about discussing sexual concerns or feelings of emotional discomfort, which a	Both patients and providers described trust as a key characteristic of a positive patient-provider relationship that could facilitate effective communication about … concerns. [p.3203, Reese et al 2017] An effective discussion about … concerns is defined as a discussion that meets patients' information needs and fosters a positive patient-provider

number of patients pointed out made them less likely to raise sexual concerns [p.3202, Reese et al 2017] Some patients remarked of a tendency of providers to refer them elsewhere if sexual concerns were mentioned rather than to discuss them, leading to the potential to feel somewhat cast aside [p.3202, Reese et al 2017] Some patients hoped their providers would specifically ask about … concerns and normalize their concerns [p.3203, Reese et al 2017] Higher levels of [patient] uncertainty and distress are associated with inadequate information, lack of understandable information, one-way communication (clinician to patient), and lack of routine symptom assessment during and after therapy, specifically discussing what symptoms are most distressful to the individual. [p.257, Tish Knobf 2013]	relationship (i.e., one that is characterized by mutual trust and respect). [p.3204, Reese et al 2017] Patients generally sought open and collaborative communication characterized by the provider raising the discussion and the patient deciding on the path of action [p.3205, Reese et al 2017] Effective communication about sexual concerns can validate patients' concerns, cement a positive patient-provider relationship, and lead to support and solutions. [p.3205, Reese et al 2017] The clinicians' engagement with the survivor … allows for the early establishment of the mutual trust that serves as a foundation for the successful promotion of active participation of survivors in their own care [p.458, Wiljer et al 2010] Given the reciprocal nature of communication, greater patient involvement is more likely to take place when physicians adopt more participatory decision-making styles [p.405, Arora et al 2009] … physician … discuss available options in a way they [patient] could understand … encourage them to express their opinion about the option they would prefer. [p.408, Arora et al 2009] A participatory decision-making style on the part of physicians may have a positive impact on patient outcomes for all patients, even those who prefer to leave the final decision up to the physician [p.410, Arora et al 2009] … physicians should make efforts to engage all their patients in the decision-making process by explaining options in an understandable manner and deliberating with patients on what option might be best for them. … Patients whose physicians adopt such a participatory decision-making style are likely to feel more empowered and experience more positive HRQOL [health-related quality of life] outcomes. [p.411, Arora et al 2009] Patients want information that they can easily understand … and they want to know what to expect and how to manage symptoms, as well as be given information at specific times during the experience, particularly information that matches their individual needs [p.255, Tish Knobf 2013]

	… if a patient receives concrete, objective, and understandable information about potential or actual symptoms, coping, adjustment, and self-management will be enhanced. [p.257, Tish Knobf 2013] … determine patient preferences for information and current understanding of the disease and treatment. This establishes the foundation for the relational exchange of information between the nurse and patient. [p.259, Tish Knobf 2013]
CMOC3: Patients and practitioners have shared understanding and expectations of their roles in self-management **Programme theory: If practitioners and patients are united in their expectations and understanding of their respective roles in the care pathway (C), then they will engage in discussions about self-management (O) because of a sense of shared responsibility (M).**	
Patient-practitioner …cancer survivors have expressed concerns that GPs may not be adequately trained to handle the complexity of their conditions. [p.405, Chan et al 2017] On the patient level, there is reservation to report pain because patients do not want to complain and keep the focus on the cure. Insufficient knowledge causes misconceptions and fears about adverse effects, addiction, and risk of tolerance … [p.2, Hochstenbach et al 2017] Barriers reported by survivors include … lack of confidence in the skills of a PCP or nurse and a survivor perception of requiring high-level specialist care. [p.185, Jefford et al 2014]	**Patient-practitioner** …patient education … suggested to ensure realistic expectations … [p.2, Hochstenbach et al 2017] Providing survivors and GPs with information, such as a survivorship care plan, guidelines for follow-up, clear communication with specialists and rapid access to specialist care, should this be necessary, improves the confidence of both patients / survivors and GPs. [p.185 Jefford et al 2014] The [patient-clinician communication] framework explicitly addresses unmet informational needs by suggesting provision of information as a relational exchange that occurs between the patient and clinician and includes active listening; attention to patient preferences; and promotion of patient participation, empowerment, and self-care. [p.256, Tish Knobf 2013]
Inter-practitioner Two reasons for inadequate team-based care … were a dearth of interdisciplinary training and a perceived lack of physician buy-in regarding the need to provide dedicated caregiver support services. … providers' perceived duplication of services could be an additional factor. For example, if medical providers feel that patients' and caregivers' psychosocial needs are already being adequately addressed by existing resources (e.g., clinic brochures and handouts, national hotlines and community resources, and family meetings to discuss goals of care, etc.), they may be less amenable to devoting additional time and precious clinic resources to providing specialized supportive care programs for caregivers. [p.277 Ratcliff et al 2019]	**Inter-practitioner** Strengthened links with colleagues in secondary care, particularly through clinical visits and 'buddying' schemes … have promoted mutual learning and strengthened relationships among primary and secondary health professionals. [p.327, Campion-Smith 2014] … better coordinated care between oncology specialists and PCPs might improve outcomes for breast cancer survivors. [p.186 Jefford et al 2014] … interdisciplinary, team-based care requires supportive care providers to be co-located in the same physical space as the medical providers, and available

… information transfer from oncologists and secondary care could improve the confidence of primary care health professionals and subsequently the care coordination of patients after cancer treatment. [p.92, Faithfull et al 2016] Challenges to [patients] keeping healthy include lack of consistent advice from providers, lack of coordination of information across providers, limited prescriptive information for healthy eating and physical activity, uncertainty of what provider to go to for what issues, and lack of expertise among oncology providers for health promotion and risk reduction. [p.259, Tish Knobf 2013]	for immediate or same-day consultations. [p.274 Ratcliff et al 2019] Use of the electronic medical record could support communication about patients among nurses across care settings. [p.259, Tish Knobf 2013
CMOC4: Organisational strategies enable practitioners to deliver self-management support interventions Programme theory: If organisations use strategies to endorse self-management support interventions (C), then practitioners are more likely to engage with them (O) because practitioners perceive those interventions are a priority in the organisation (M).	
On the organisation level, fragmentation of care due to different health professionals in different care settings complicates coordination and continuity of care. [p.2, Hochstenbach et al 2017] Barriers for integrating caregiver support into clinical care included inadequate funding, lack of interdisciplinary training among providers, and concern that research-based interventions are often not flexible enough to roll out into clinical practice. [p.264, Ratcliff et al 2019] Although such tools [treatment summaries, survivorship care plans] have been introduced within the UK their use is unclear and there is still substantial work to be undertaken for this information to disseminate from secondary care to the community practitioner. [p.92, Faithfull et al 2016] … current long-term survivorship services and levels of perceived confidence among nurses and allied health professionals are variable between professional groups and individual practitioners. [p.93, Faithfull et al 2016]	Nurses have access to all patient data to facilitate patient handover and guarantee continuity of care. [p.6, Hochstenbach et al 2017] Healthcare technology … allows interventions to be tailored to the individual patient and the situation for which support is required. [p.2, Hochstenbach et al 2017] … with structured support, specific cancer-related education and the development of communication skills, practice nurses are very well placed to take on an increasingly prominent role in providing support for people after primary cancer treatment. [p.327, Campion-Smith 2014] Survivors report the SCP would promote self-management by helping monitor for late effects, adopt healthy behaviors and undergo appropriate follow-up and surveillance. [p.188 Jefford et al 2014] … to be maximally effective and conserve resources, routine screening for supportive care needs should be followed by stepped care, such that caregivers with low supportive care needs receive no or low intensity intervention (e.g., psychoeducation or support group referrals), and those with high intensity supportive care needs receive more intensive interventions (e.g., individual counselling). [p.274, Ratcliff et al 2019] … targeting the highest risk (and highest cost) patients and caregivers may facilitate demonstration of impact. [p.275, Ratcliff et al 2019]

	… telephone or online modalities could potentially provide the flexibility and convenience required to meet the needs of already overburdened caregivers and utilize fewer healthcare resources (e.g., provider time, clinic space) than in-person delivery. [p.277, Ratcliff et al 2019] Community nurses need confidence in the treatment summaries and care plans so as to understand the long-term consequences of cancer treatment. Implementing these tools could raise awareness of the long-term care needs of cancer survivors and improve community nurses' confidence in providing care to this group of patients. [p.92, Faithfull et al 2016]
CMOC5: Health systems are configured to integrate self-management support interventions into routine care Programme theory: If systems are configured to integrate self-management interventions into routine practice (C), then interventions are more likely to be sustainable (O) because of ease of delivery (M).	
Across stakeholder groups, interviewees noted a mismatch between the perceived needs of informal family caregivers, and the existing supportive care available to them. … integrating a caregiver intervention … into a palliative or oncology setting would not be duplicating services, and that it may be well received by stakeholders … as filling a noticeable gap in care. [p.276, Ratcliff et al 2019] Fragmentation of care due to different health professionals in different care settings complicates coordination and continuity of care [p.2, Hochstenbach et al 2017] The potential involvement of multiple GPs can lead to confusion in the expected roles under the shared care model. The clear definition of provider roles in survivorship care prevents duplication of care and ensures that care does not fall through the cracks as a result of miscommunication between providers [p.409, Chan et al 2017] … common barrier reflected by community practitioners was the lack of time to manage survivorship issues due to a high daily patient load [p.407, Chan et al 2017] … most healthcare systems do not currently have the infrastructure in place to routinely screen caregivers for distress and other unmet needs. [p.277 Ratcliff et al 2019]	Specifically, they [practitioners] valued short (i.e., less than six sessions), modifiable (e.g., flexible length and content) interventions that could be tailored to caregiver need. [p.277, Ratcliff et al 2019] … interventions … may need to use adaptive designs, changing in intensity, duration, and focus based on what is best for the recipient at a given time. [p.277, Ratcliff et al 2019] … telephone or online modalities could potentially provide the flexibility and convenience required to meet the needs of already overburdened caregivers and utilize fewer healthcare resources (e.g., provider time, clinic space) than in-person delivery. [p.277, Ratcliff et al 2019] Another important … factor was the availability of a competent referral source for a provider which—if present—could facilitate clinical discussions [p.3203, Reese et al 2017] To circumvent the lack of time to manage survivorship issues in the community, dedicated GPs can be hired solely to run survivorship clinics [p.410, Chan et al 2017] … GPs recognised the importance of the extra nurse support … One GP mentioned the positive effect it had on the patients seen in clinic, without any noticeable impact on own workload, and another GP estimated that the

… inadequate funding for supportive cancer care. …there is no reimbursement for caregiver education or training in symptom management [p.277 Ratcliff et al 2019]	intervention may have reduced the number of times patients came to seek an appointment. [p.8, Stanciu et al 2019] … attempts to integrate family-based care should be accompanied by top-down support, in the form of physician champions (i.e., physician leaders promoting care integration). [p.274, Ratcliff et al 2019]

Appendix J. Ethics approval letter for Chapter 5

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

Miss Kumud Kantilal
PhD student in Pharmacy Practice
University of East Anglia
School of Pharmacy
University of East Anglia
Norwich
NR4 7TJ

West of Scotland REC 4
Research Ethics
Ward 11, Dykebar Hospital
Grahamston Road
Paisley
PA2 7DE

Date 11 November 2020
Direct line 0141 314 0213
E-mail WoSREC4@ggc.scot.nhs.uk

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

Dear Miss Kantilal

Study title:	**Designing Services for Cancer in Older People (DiSCO): A study to co-design a self-management support intervention for older people living with and beyond cancer**
REC reference:	**20/WS/0163**
Protocol number:	**R207923**
IRAS project ID:	**279388**

The Research Ethics Committee reviewed the above application at the meeting held on 06 November 2020. Thank you for attending to discuss the application with Professor Wendy Hardeman via Zoom Video Conferencing.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Number	Condition
1	For administrative purposes, it is paramount that supporting documents are properly version controlled. As such, it would be useful if the following documents have a document date and version number contained within the documents i.e. in a footer rather than just within the file path: a. Topic guide for Workshop (Appendix F) b. Topic guide for focus group (Appendix E)

	c. Invitation, outcome, reminder (Appendix A) d. Expression of interest (Appendix C) e. Consent form (Appendix D) f. PIS combined (Appendix B) Also it is advisable to remove protocol appendices - A to F as they are individually approved and in future any changes to these documents will always warrant updates to the protocol which is not necessarily ideal.
	Recommendation
1	Update the email address on the expression of interest form – appendix C to correct the documented error.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS using track changes. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs), except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We routinely audit applications for compliance with these conditions.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC Sites

The favourable opinion applies to all NHS/HSC sites taking part in the study taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland)being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UEA liability insurance]		01 June 2020
Interview schedules or topic guides for participants [Workshop process and activities]	1.0	21 September 2020
Interview schedules or topic guides for participants [Focus group topic guide]	1.0	21 September 2020
IRAS Application Form [IRAS_Form_07102020]		07 October 2020
Letter from funder [PRUK letter]		06 January 2020
Letter from sponsor [UEA letter]		06 October 2020
Letters of invitation to participant [Invitation, outcome and reminder emails]	1.0	21 September 2020
Letters of invitation to participant [Expression of interest forms]	1.0	21 September 2020
Other [UEA professional indemnity]	N/A	01 June 2020
Other [Confirmation from Sponsor that REC review is needed]		
Participant consent form [Consent form]	1.0	21 September 2020
Participant information sheet (PIS) [Participant information sheets]	1.0	21 September 2020
Research protocol or project proposal [DISCO protocol]	1.0	21 September 2020
Summary CV for Chief Investigator (CI) [CV]		15 September 2020
Summary CV for student [Student CV]		15 September 2020
Summary CV for supervisor (student research) [Supervisor CV]		20 July 2020
Summary CV for supervisor (student research) [Supervisor CV]		

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 279388	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Abibat Ackwumi

On behalf of
Dr Ken James
Chair

Enclosures:	List of names and professions of members who were present at the meeting and those who submitted written comments
	"After ethical review – guidance for researchers
Copy to:	Ms Maya Kumar Lead Nation England: approvals@hra.nhs.uk

West of Scotland REC 4

Attendance at Committee meeting on 06 November 2020

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr Alistair Brown	Consultant Surgeon	Yes	
Dr Wendy Cohen	Speech & Language Therapist	Yes	Chair of Meeting
Dr Rosemarie Davidson	Consultant in Clinical Genetics	No	
Miss Natalie Elliott	Student Nurse	Yes	
Dr Michael Fail	Consultant Geriatrician	No	
Dr Kay Greenshields	Senior Scientific Officer	No	
Dr Ken James	Consultant Anaesthetist	Yes	
Dr Grigorios Kotronoulas	Lecturer	Yes	
Dr Sean MacBride-Stewart	Medicines Management Resources Lead for Pharmacy Services	Yes	
Dr Rachael MacIsaac	Senior Biostatistician	Yes	
Mr Jim McHugh	Independent Financial Advisor	Yes	
Dr Mark McJury	Consultant Clinical Scientist	Yes	
Dr Christine Milligan	Retired - Pharmaceutical Industry	Yes	
Mr John Woods	Retired Project Co-ordinator	No	
Ms Patricia Young	Retired Business Manager	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Abibat Adewumi-Ogunjobi	REC Manager
Dr Judith Godden	Scientific Adviser
Ms Julia Hamilton	Trainee Solicitor (Observer)

Appendix K. Topic guide for discovery workshops for Chapter 5

DiSCO: Designing Services for Cancer in Older People

A study to co-design a self-management support intervention for older people living with and beyond cancer

Aims of the discovery workshop:

1. Test programme theories developed in the realist review by identifying the barriers to and enablers of practitioner-led self-management support to older people living with the long-term consequences of systemic anticancer treatment.
2. Identify the strategies used to address barriers in primary/community care settings.

Time (min.)	Discovery workshop activities	Proposed questions
10	• Outline purpose of session • Explain ground rules for the online discussion	Are there any questions before we begin?
10	• Introductions by participants	Please confirm your name for the recording.
15	• Researcher presents the practitioner behaviour(s) targeted for change, based on previous work (i.e., realist review)* * Participants provided with summary before the focus group.	1. What are your initial thoughts about the presentation?
40	• Identify barriers to and enablers for changing practitioner behaviour(s) to deliver a self-management support intervention in primary care	2. What currently stops you from offering self-management support to older people living with and beyond cancer. 3. In your view, what would need to be in place to help practitioners support older people to self-manage the long-term problems of anticancer treatment?
10	BREAK	
25	• Researcher summarises key strategies raised by participants to address barriers at: o Macro level – organisational/ policy/ health system	4. You have identified what needs to be in place to help you to support self-management. Is there anything missing?

		○ Meso level – practitioner-patient interface ○ Micro level – individual practitioner • Researcher asks participants to comment on any further strategies not yet discussed to support implementation of self-management support interventions in primary care.	Prompts: • What organisational/wider system changes will be needed to deliver a self-management support intervention? • What practitioner support or training might be required to deliver the intervention?
10		• Invite attendees to ask questions or make final comments • Thank participants for their time and contributions • Explain the next steps of the project • Invite participants to consider participating in the co-design workshops • Invite participants to complete an online feedback form	

 Member of the research team  All participants

Appendix L. Patient personas used in co-design workshops for Chapter 5

- Age 72 with prostate cancer and osteoporosis
- Winston is on hormone injections for his cancer and takes tablets to strengthen his bones.
  - He gets his hormone shots every 3 months from his GP and collects his bone tablets from the local pharmacy every 2 months.
  - He sometimes gets hot flushes and often feels tired since starting the hormones.
    - Winston's GP gave him some tablets for the hot flushes if they get too bad.
    - He was told to exercise to help with tiredness but doesn't feel motivated to go out and exercise on his own.
- Winston lives alone but has support from his church.
- Winston feels he is managing fine on his own but would like to talk to other people like him.

- Age 68 with bowel cancer. He has no other health issues.
- Alan had radiotherapy and chemotherapy, which finished about two years ago.
  - Alan suffers from periodic bowel incontinence since finishing treatment.
- Alan was very active before he had cancer but does not go out much now because he doesn't know when he might need the toilet. This makes him feel very depressed.
- About a year ago Alan attended a course run by Macmillan Cancer Support, called HOPE (Help to Overcome Problems Effectively), but didn't like being with people with other cancers.
- Alan lives with his wife who provides regular support for his health.

- Age 82 with breast cancer. She also has diabetes and hypertension, which are managed with tablets.
- Bibi finished chemotherapy about 5 years ago and has struggled with remembering things and nerve damage ever since.
  - The nerve damage has affected Bibi's balance and walking so she is scared to leave the house on her own. Bibi already had nerve problems because of her diabetes, but things are worse since the cancer treatment.
  - Bibi loved to cook in the past, but since the cancer treatment she can't remember the recipes, which makes her sad.
- Bibi wants to do more by herself but says that her mind and body 'let her down.'
- Bibi can't speak English so someone from her family always goes with her to health appointments.
- Bibi's husband died ten years ago, and she lives with her two sons and their families.