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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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ABSTRACT

Introduction Self-management support can enable and empower people living with and beyond cancer to take an active role in managing long-term consequences of cancer treatment. Healthcare professionals are key to promoting patients to self-manage, however, they do not routinely engage in these discussions. This review aims to understand what works for whom and in what circumstances in relation to practitioners engaging with supporting people living with and beyond cancer to self-manage long-term consequences of systemic anticancer treatment.

Methods and analysis We will follow five steps for undertaking the realist review: (1) define the review scope, (2) develop initial programme theories, (3) evidence search, (4) selection and appraisal and (5) data extraction and synthesis. We will combine an informal literature search with a theory-based approach, using the theoretical domains framework, and stakeholder feedback to develop initial programme theories. We will search Medline, EMBASE, CINAHL, Scopus, PsycINFO, ERIC and AMED databases to September 2019, and supplement this with citation tracking, grey literature and practitioner surveys. Data selection will be based on relevance and rigour. Data will be extracted and synthesised iteratively, and causal links between contexts, mechanism and outcomes illuminated in the process. The results will be reported according to the Realist And Meta-narrative Evidence Syntheses: Evolving Standards quality and publication standards.

Ethics and dissemination We have received ethical approval through the Research Ethics Committee, Faculty of Medicine and Health Sciences, University of East Anglia (ref 2 01 819-124). We will disseminate to the research community through conference presentations and a peer-reviewed journal article. We will work with healthcare organisations, cancer charities and patients to agree a strategy for disseminating to these groups.

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Strengths and limitations of this study

► The realist review addresses a policy initiative in the UK to promote self-management among people living with and beyond cancer.
► The methodological approach of combining published with survey data is novel to a realist review.
► Using the theoretical domains framework is a novel approach for the initial development and continuous refinement of programme theories in realist methods.
► A limitation is that only English language studies will be included.

9 million deaths,[1] costing an estimated £115 billion.[2] The global cancer burden is putting significant physical, financial and emotional strain on people living with cancer and their families. At the same time, coping with the growing demand for cancer care is becoming untenable for healthcare systems in high-income, middle-income and low-income countries. This is due to increasing treatment complexity, rising healthcare costs and a shrinking healthcare workforce.[2–4]

In the UK, a growing and ageing population, earlier detection strategies and newer and more effective targeted treatment options are leading to increasing numbers of adults being diagnosed with and living beyond cancer. The number of people living with and beyond cancer is predicted to grow from 2.9 million in 2020 to 5.3 million in 2040 of whom more than 70% will be over 65 years.[5] It is estimated that about one in three adults will be living with the long-term consequences of cancer treatment, which can last for years after cancer treatment.[6] Systemic anticancer therapy is one type of cancer treatment. Choice of systemic anticancer therapy

INTRODUCTION

The global cancer incidence in 2018 was estimated at 18 million new cases and over

can vary depending on cancer type and whether treatment is intended to be curative or palliative and includes chemotherapy, hormonal therapy, targeted therapy, such as small-molecule drugs or monoclonal antibodies, and immunotherapy. While advances in systemic anticancer therapy have led to improvements in survival, a significant proportion of people living with and beyond cancer will experience long-term problems associated with systemic anticancer therapy.[7–9] The consequences can be both physical, such as urinary and bowel problems, pain and chronic fatigue, and psychosocial, such as fear of cancer recurrence, depression, negative body image and issues with relationships.

Self-management involves the actions taken by patients to recognise, treat and manage their long-term health conditions.[10] This may include physical activity to improve fatigue, self-medication to manage pain and attending self-help groups for information and emotional support. Self-management therefore requires patients to be an active partner in their healthcare. A large body of research has evolved to investigate and address patient barriers and enablers to self-managing long-term conditions.[11–13] Enablers include increasing patient confidence, a person-centred approach and a collaborative partnership between patients and healthcare providers. Despite primary and secondary care practitioners, such as doctors, nurses, pharmacists and allied health professionals having a key role in supporting patient self-management, implementation of this supportive role beyond research studies is limited.[14 15] Practitioners providing cancer care do not routinely provide self-management support to people living with and beyond cancer. This is likely due to lack of clarity around optimal implementation approaches.[16] Application of behaviour change theory may help to better understand the barriers and enablers to practitioners implementing self-management support and addressing these through relevant behaviour change techniques.[17] Furthermore, identifying intervention components that will maintain effectiveness beyond the research phases requires an understanding of why intervention components work and how its efficacy is influenced by contextual factors such as available resources and training.[18]

Realist reviews use theory to explore how context such as cultural norms and values, economic conditions, geographic characteristics or national policy interacts with various mechanisms to produce outcomes. Further, a realist review can produce important information about the relative effectiveness of intervention components, thereby enabling practitioners, researchers and service providers to design and implement interventions comprising only effective components for particular contexts.

With self-management as a key strategy for ensuring personalised care for people living with and beyond cancer,[19 20] this review will be timely in building the evidence base to identify the principles for changing practitioners' knowledge, attitudes and behaviour to facilitate engagement with and delivery of self-management support interventions. We will focus on interventions designed to support patients living with and beyond cancer to self-manage the long-term consequences of systemic anti-cancer therapy.

METHOD AND ANALYSIS
Realist review
A realist review is an interpretative theory-driven approach to synthesise evidence using multiple sources such as published studies, policy documents and grey literature.[21] The realist approach acknowledges that interventions may work in some contexts but not others. This notion of interventions being context-bound is a key principle of the realist approach. A realist review focuses on causation and is represented as context+mechanism=outcome.[22]

Context refers to the 'backdrop' conditions that have an impact on outcomes, such as the way services are configured to facilitate practitioners to support self-management by patients. Other examples of context include cultural norms and values, pre-existing relationships/rapport between practitioners and patients and funding sources. Context can be understood as any condition that triggers or modifies a mechanism.[23] A mechanism is the causal force, triggered in particular contexts, that leads to outcomes. Mechanisms explain why and how observed outcomes occur and usually comprise two parts: the 'resources' offered by an intervention and the cognitive or emotional decisions ('reasoning') and behaviour of people.[24] Examples of 'resources' include practitioner information or advice and examples of 'reasoning' include trust between practitioner and patient and increased practitioner confidence to provide self-management support. Outcomes are the intended or unintended effects of the intervention, which are based on the interaction between the context and mechanism. Some examples of outcomes include patient engagement with self-management activities and practitioners formulating an individualised self-management action plan with the patient.
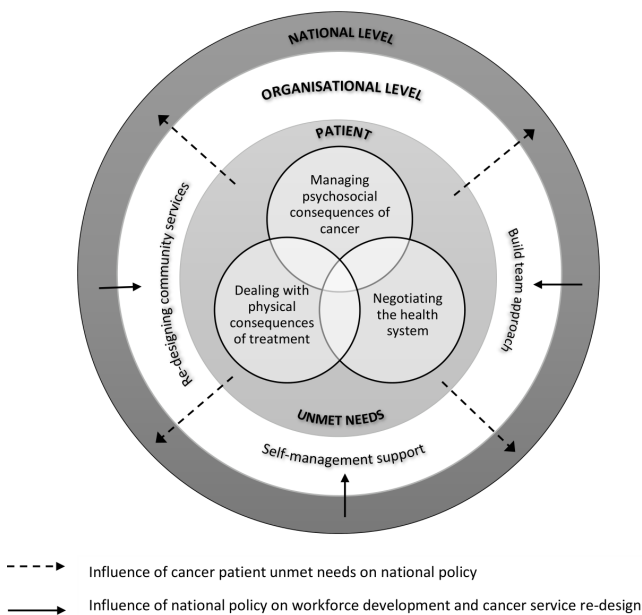
A realist review begins with programme theories which describe a theoretical relationship between contexts, mechanisms and outcomes. Use of formal theory from disciplines such as sociology and behavioural science has emerged as a strategy to providing a framework for the initial generation of programme theories.[25] These programme theories are then tested against empirical evidence to explain 'How does it work?', 'Why does it work?', 'For whom does it work?' and 'In what circumstances does it work?'[21]

This testing is an iterative process of examining evidence to develop ideas which is termed abductive reasoning,[26] together with illuminating the causal links between contexts, mechanisms and outcomes termed retroduction.[27] This process results in a middle-range theory to explain how the interventions included in the review work. The middle-range theory is sufficiently broad to allow transferability or portability to similar interventions[28] and
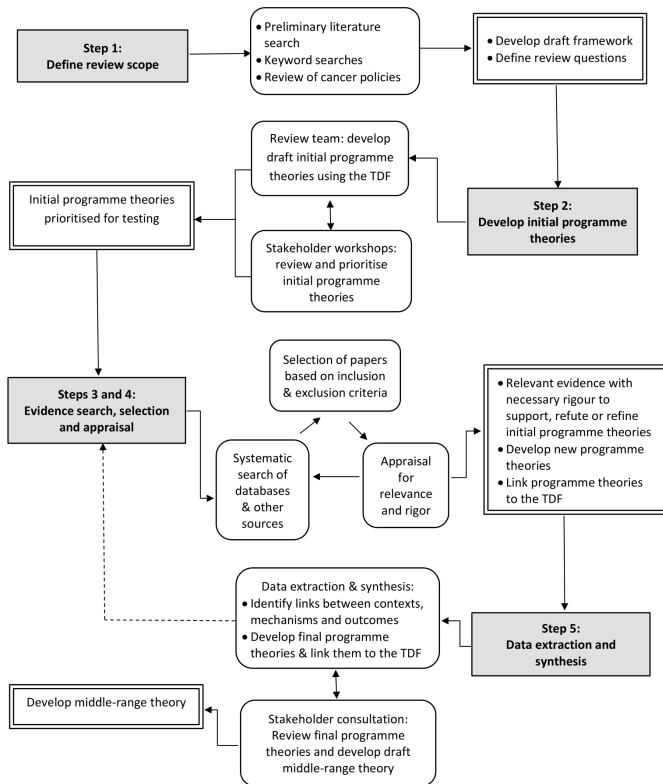
Figure 1 Overview of realist review design. TDF, theoretical domains framework.

that can be used to design and implement interventions within complex environments.[27] Stakeholder engagement throughout the review process is encouraged to ensure inclusion of multiple perspectives.[22] Reporting standards for realist reviews and evaluation have been developed,[29]

----> Influence of cancer patient unmet needs on national policy

——> Influence of national policy on workforce development and cancer service re-design

Figure 2 Framework of the influences on unmet needs of people living with and beyond cancer.

however, specified methods for conducting realist reviews are variable.[22 26 30]

The main research question guiding this review is:

What works for whom and in what circumstances in relation to practitioners supporting people living with and beyond cancer to self-manage the long-term physical and psychosocial consequences on completing systemic anticancer therapies?

Pawson *et al* have proposed a method for conducting realist reviews.[21] However, there is freedom to interpret the method and customise the steps.[22 26 29] This review is guided by five steps, adapted from Pawson *et al* for conducting a realist review: (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.[21] Figure 1 provides an overview of the review design. Steps are shown sequentially, however, as the process of undertaking a realist review is iterative, steps may overlap or proceed in parallel as the review progresses. We will report the study results according to the Realist And Meta-narrative Evidence Syntheses: Evolving Standards (RAMESES) quality and publication standards.[30]

Step 1: define the review scope

A realist review starts by clarifying the scope of the review and developing initial programme theories, which provide the scaffolding for evidence synthesis.[21] We undertook a preliminary literature search to identify the existing literature about influences on practitioners promoting self-management among patients and how self-management support interventions seek to address the needs of people living with and beyond cancer. We started by looking at systematic reviews of self-management and self-management support in adults living with and beyond cancer. To identify relevant reviews, we searched PubMed and The Cochrane Library, using the following search terms: cancer survivors, healthcare professionals and self-management or self-care. In addition, we undertook keyword searches on Google Scholar and the National Institute for Health and Care Excellence Evidence search for reviews and primary studies on self-management support in the cancer setting and we reviewed national and international cancer policy documents.[4 31–33]

The preliminary search informed the construction of an overarching framework (figure 2). We drew mainly on the UK[31 32] and the USA[4 33] recommendations to improve the care of people living with and beyond cancer and the experiential knowledge of the review team. We identified the key issues faced by people who had completed cancer treatment and strategies proposed in the UK to address peoples' needs. The framework highlights key unmet needs of people post cancer treatment: dealing with the physical and psychosocial consequences of cancer treatment and negotiating the multiple cancer services offered within the healthcare system as seen in figure 2. The framework shows the influences on the unmet needs of people at a policy level. The framework sets out changes

needed in cancer services and the healthcare workforce to facilitate a shift from a medical-led approach to one that empowers people living with and beyond cancer to take on a more active role to self-manage the consequences of cancer treatment, with support from practitioners.

The realist review questions which emerged from the preliminary search were:

1. What are the determinants (barriers and enablers) of practitioners delivering interventions to support self-management by people living with and beyond cancer?
2. What are the key components, practitioner skills and behaviours needed to implement self-management support interventions among people living with and beyond cancer?
3. What are the intended and unintended outcomes for patients, organisations or the wider healthcare system of interventions which target practitioner delivery of self-management support?
4. What are the mechanisms by which interventions targeting practitioner delivery of self-management support result in their outcomes?
5. What are the contexts that influence mechanisms involved in interventions targeting practitioner delivery of self-management support?

Step 2: develop initial programme theories

Programme theories are abstract descriptions of the content or components of interventions and how they are assumed to cause intended or observed outcomes.[25] Realist programme theories illustrate the relationship between contexts, mechanisms and outcomes. They are expressed as context–mechanism–outcome configurations (CMOCs). Figure 3 shows hypothesised CMOCs using self-management support as an example. Various methods are used to articulate and build initial programme theories, such as extracting implicit theories from empirical evidence or stakeholders and using concepts from a priori formal theories. Given the heterogeneity and abundance of formal theories, selection
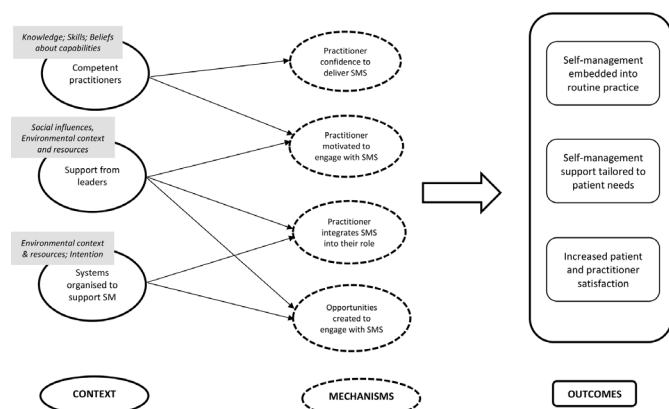
Figure 3 Hypothetical self-management support programme theory illustrating context–mechanism–outcome configurations. Grey boxes represent TDF domains. SM, self-management; SMS, self-management support; TDF, theoretical domains framework.

of appropriate theories for realist reviews can be challenging. Using a framework that incorporates a wide range of theories could provide a broad lens to identify influences on programme delivery.[25]

We will structure ideas about programme theories developed from our preliminary search in step 1, with the theoretical domains framework (TDF). This framework was developed by experts from multiple disciplines, including behavioural science and implementation science and is widely used in healthcare to identify barriers and facilitators of practitioner behaviour change.[34 35] 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.[34] Figure 3 includes the TDF domains for the hypothesised CMOCs.

Benefits of using the TDF to build initial programme theories include: identification of a broad range of influences on practitioner behaviour to support self-management in people living with cancer than would be possible using empirical evidence alone; exploration of the influence of context at different levels such as individual, team, organisational and system; and provision of a structured, yet flexible, approach to building programme theories.

We will seek the help of stakeholders to review and prioritise a maximum of 10 initial programme theories to test against the literature. Stakeholders will be recruited from existing cancer support and research groups known to the researchers. Membership of the groups includes people living with and beyond cancer, caregivers, practitioners, healthcare purchasers, that is, commissioners and members of cancer advocacy groups such as cancer charities. Stakeholders will prioritise the initial programme theories using a two-step process: by completing an online survey to identify what they perceive to be important about how self-management programmes delivered by practitioners such as nurses, doctors, allied health professionals and pharmacists to support people with cancer worked, and during a face-to-face workshop to identify up to a maximum of 10 initial programme theories for further testing.

The review team will select programme theories for further discussion, based on an a priori criterion of 70% stakeholder agreement.[36] Initial programme theories will be prioritised as follows: if 100% of survey participants agree that the theory is important it will be selected for testing. If 70%–99% of survey participants agree that the theory is important it will be discussed at a workshop. If less than 70% of participants agree that the theory is important it will not be selected.

Step 3: evidence search

This step will involve the identification of suitable papers to test and refine the initial programme theories selected

Table 1 Review inclusion and exclusion criteria

Inclusion criteria

P—Population	Practitioners, for example, doctors, nurses, pharmacists, allied health professionals, supporting self-management in adults living with and beyond cancer. Patient, caregiver or manager perspectives on practitioner implementation of support of self-management consultations in adults living with and beyond cancer.
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, for example, knowledge/skills/behaviours needed to support self-management and signposting patients. Patients, for example, adjustments/acceptance of self-management, shared decision making, relationships with practitioners. Process or implementation outcomes, for example, health service use, change in care delivery.
H—Healthcare context	Any healthcare setting that provides care to adult cancer populations, for example, hospital, ambulatory care, outpatient care, community services/organisations, primary care practice, digital (eg, telehealth, app-based or web-based).

Study design

► No restriction on study design.
► Include non-empirical sources (ie, grey literature), for example, opinion papers, books, guidelines, policies, editorials, dissertations and so on through citation searches and identification by the review team and our 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.

in step 2. We will search the following electronic databases, to September 2019: Medline, EMBASE, CINAHL, Scopus, PsycINFO, ERIC and AMED. Search terms will be developed in discussion with the review team (see online supplementary file for an example of Medline search).

In addition, we will undertake the following to identify relevant evidence from a range of sources for inclusion in the review:

► Check reference lists from primary studies and systematic reviews (snowballing).
► Citation searches, for example, using the 'Cited by' option on Scopus and Google Scholar (lateral searching).
► Seek input from the review team to uncover other relevant publications, guidelines or policies.
► Seek input from stakeholders representing practitioners, such as doctors, nurses and pharmacists, and commissioners of self-management support interventions for people living with cancer, via an online survey.

Table 1 reports the inclusion and exclusion criteria we have developed to focus the review, but these will likely be refined as the review progresses.

We acknowledge that further iterative searches may be needed as the review progresses. This will involve

purposive searching for evidence to support or refute the initial or emerging programme theories.

The traditional data source for realist reviews is secondary data from published documents. This approach dominates realist literature and is useful for exploring interventions that have limited published real-world data. In such instances, reviewers use data from related interventions. Where interventions are widely implemented, combining real-world experience with published data may provide clearer insights into the mechanisms that operate in particular contexts to produce outcomes. We will develop an online survey to capture real-world data of interventions which target practitioner delivery of self-management support in any healthcare setting. We will adopt the strategies used for conducting realist qualitative interviews to develop our realist theory-driven survey questions.[37] Survey questions will be open-ended, producing qualitative data. We will use a purposive sampling approach to identify potential survey respondents. These will include members of national and international cancer societies, whose membership include practitioners from primary, community and secondary care settings, such as the British Oncology Pharmacy Association, UK Oncology Nursing Society and Clinical Oncology Society of Australia, and research and

advocacy groups involved with developing or evaluating self-management support services for people living with and beyond cancer.

We will send a link of the survey via email to invite potential participants to share their experiences. We will collect data 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. Completion of the survey will be voluntary. Only the research team will have access to the personal details of participants, which will be kept secure. Participants will be able to withdraw at any point, without giving a reason. All data will be destroyed or fully anonymised when no longer needed.

Step 4: selection and appraisal of evidence

We will use systematic methods for study screening and selection, using Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidance.[38] Two reviewers (KK and HW) will independently screen papers first by title and abstract and then full text. Papers in a non-English language will be excluded at title and abstract screening stages. Disagreements will be resolved by discussion with a third reviewer to ensure that there is consistency in paper inclusion. Depending on the number of papers retained, further refinement of the review scope may be decided by the review team. The review team will decide on new or revised selection criteria as the need for additional searches arises. These will likely depend on whether the additional studies can contribute to refinement of programme theories.

Inclusion criteria in realist reviews are whether the reported evidence has enough rigour and relevance to inform the development of CMOCs.[21] Documents will be selected based on relevance to contributing to programme theory development or testing. We have developed criteria to rank the relevance of studies to help with the initial study selection process. Table 2 summarises the ranking criteria for relevance that will allow the review team to distinguish between conceptually rich and weaker evidence for providing explanations for programme theory development. We will also review documents for rigour in terms of credibility and trustworthiness, as outlined by the RAMESES standards.[28] We will include studies if deemed 'good enough' by the review team 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.[22] Realists argue that the traditional evidence hierarchy is not applicable when undertaking realist reviews or evaluations.[27 39] Useful causal information can arise from seemingly poor quality studies that can provide rich insights for programme theory development.[39] We will hence consider evidence of lesser quality if relevant for developing our programme theories.

Step 5: data extraction and synthesis

We will develop and pilot a bespoke Excel data extraction form. Data will be independently extracted by two reviewers and will include the following: study aims, design and methods, study participants (eg, people living with and beyond cancer, healthcare practitioners), study outcomes and information relevant to programme theories and emerging CMOCs. As per the realist approach, data will focus on author explanations and discussions about how an intervention was assumed to work or not.

Table 2	Criteria to rank likely relevance of study to theory development
High relevance	▶ Relates to adults living with and beyond cancer and describes the implementation of a self-management support activity initiated by practitioners or targeting practitioner behaviour change. ▶ Relates to supporting people living with and beyond cancer and describes training of practitioners in providing self-management support. ▶ Relates to supporting people living with and beyond cancer 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 people living with and beyond cancer.
Moderate relevance	▶ Relates to people living with and beyond cancer and includes description of patient experience of interacting with practitioners supporting self-management. ▶ Describes experiences of people living with and beyond cancer 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 people living with and beyond cancer described but involvement of practitioner in its delivery is unclear. ▶ Describes implementation of practitioner-led self-management support activity during other stages of the cancer journey (ie, not the survivorship stage). ▶ Quantitative data on self-management support intervention. ▶ Describes self-management support needs of people living with and beyond cancer.
No relevance	▶ Does not meet any of the above criteria.

Individual papers may include segments that contribute to the different parts of a programme theory and therefore may need several readings to extract applicable data.

Sections of relevant text from papers and the online survey will be coded and imported into the Excel data extraction form. Some codes will originate from the papers and the online survey (inductive codes) and others from the initial programme theories (deductive codes). Coded text will be based on whether the evidence refers to context (C), mechanism (M) and/or outcome (O).

We will extract and code data from qualitative, quantitative and mixed methods studies separately. The extracted coded text from different study designs will then be synthesised together according to the relationship between contexts, mechanisms and outcomes and to identify any emerging patterns of contexts and outcomes and the possible mechanisms.[22 40] Data synthesis will involve reflection and discussion among the review team. We will question the integrity of each programme theory by examining if it is supported by empirical evidence, adjudicate between competing programme theories, consider the same programme theory in different settings and compare the programme theories to practical experiences of practitioners and patients.[40] We will further attempt to link our programme theories to the TDF or another formal theory that may help to explain the patterns emerging from the CMOCs. We will use data from the papers and online survey to confirm, refute or refine the programme theories.

We will convene a workshop, to discuss our findings with stakeholders, which include practitioners, patients, caregivers and policymakers. The final output of the review will be a refined theory, called a middle-range theory that will highlight the key contextual factors and mechanisms involved in interventions, delivered by practitioners, to support self-management in people living with and beyond cancer. It is important to recognise that this review will focus on a subset of prioritised programme theories, resulting in a middle-range theory that will represent partial knowledge. This potential limitation of realist reviews is widely accepted due to the restricted ground that can be covered by any single review.[21]

We will combine published data with real-world experiences. Where interventions have been implemented widely, this innovative strategy may offer a methodological advancement over the traditional exclusive use of published/grey literature in a realist review. Combining this real-world experience with published data may provide clearer insights into the mechanisms that operate in particular contexts to produce outcomes. Our findings will be used to inform future work to co-design an intervention targeted at practitioners to support people living with and beyond cancer to self-manage the long-term consequences of systemic anti-cancer therapy.

PATIENT AND PUBLIC INVOLVEMENT
Members of the public were not involved in development of this protocol.

ETHICS AND DISSEMINATION
This project has been reviewed by the University of East Anglia research ethics committee (ref 2 01 819-124, approved on 12 August 2019). We will disseminate the findings via a peer-reviewed journal article, conference presentation(s) and a report to Pharmacy Research UK, who funded the review.

The findings will be used to inform the next stage of the project and have the potential to benefit multiple stakeholders involved in developing, implementing and evaluating interventions to support self-management support among people living with and beyond cancer.

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