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How Do Self-Examination Interventions For The Early Detection of Cancer Work? An Umbrella Review Protocol.

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Protocol

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Abstract

Background: Cancer is a major contributor to mortality and morbidity globally. A key prognostic factor for many cancers is early detection. Self-examination is often promoted as a method to detect cancer early for cancers that have early physical signs and symptoms. The type(s) of interventions capable of delivering behaviour change such as self-examination are complex with their description historically lacking. This umbrella review protocol sets out the methodology for summarising the evidence surrounding self-examination for four major cancers; breast, testicular, oral and skin. The review aims to answer the following question: What are the components of self-examination programmes for early detection of cancer and are they effective in bringing about actions that could lead to early detection of cancer in post pubescent people.

Methods: The methodology has been informed by the PRISMA-P checklist for systematic reviews and the JBI methodology for umbrella reviews. Narrative synthesis will include detail on effectiveness of interventions alongside coding of intervention components using Intervention Taxonomy and the Behaviour Change Technique Taxonomy Version 1. AMSTAR-2 will be used to assess quality of included studies.

Discussion: The review will provide a summary of the existing evidence with descriptions of interventions whilst identifying gaps for future research in this area.

Registration: Prospero: CRD42021285966

Background

Cancer continues to be a major cause of death globally. The Global Burden of Disease Study estimates there are 9.6 million deaths annually attributed to cancer with an increase in incidence of 33% over a ten-year (2007-2017) period (1). In Europe it is estimated that there are 1.9 million deaths annually attributable to cancer (2). Cancer Research UK estimates there to be 166,000 deaths from cancer each year in the UK (3). When compared to other non-communicable disease, cancers are ranked 2nd in terms of contribution to disability adjusted life years for both sexes globally (1).

The aetiology of cancer varies from cancer type with each being associated with modifiable and non-modifiable risk factors. An example of a modifiable risk factor is tobacco and its association with lung cancer having been found in the 1950s (4). Other cancers for which tobacco use has been associated with over time include oral and trachea cancer (5). Obesity and heavy alcohol intake are further examples of modifiable risk factors associated with cancer (5, 6). Non-modifiable risk factors include family history, age, and genetics. For example, breast cancer has been associated with a family history of the disease and like most cancers incidence increases with age (7).

Primary prevention aims to remove the risk of developing a disease by removing or avoiding known modifiable risk factors. Four in ten cancers in the UK can be associated with modifiable risk factors (8).

An example of public health measures to bring about primary prevention include smoking bans in public areas with more focused interventions to reduce risk at individual level that might include smoking cessation services (9). Other examples include minimum unit pricing of alcohol (10).

Early detection of many cancers is an important prognostic factor. There are a range of methods that can aid early detection including screening programmes, technical devices, testing systems and self-examination. Cancer is a global problem seen in low income, middle income and high-income countries. High income countries can often afford to have national screening programmes such as breast cancer and bowel cancer screening, but low-income countries do not have the same resources to implement such programmes. More research on accessible, affordable and effective early detection methods is required.

Some cancers have physical signs and symptoms that patients can self-examine for and detect. For example, ulcers that do not heal in the oral cavity or moles that change size on the skin. Public facing campaigns often focus on raising awareness of signs and symptoms with some promoting self-examination on a regular basis. In the UK there are various programmes focused on promoting self-examination for a range of cancer types. Governmental and non-governmental organisations provide varying advice on how to self-examine, when to do it and what signs/symptoms to assess for (11–13). Some of the programmes are more widely adopted and advanced with others lacking depth, an evidence base or underpinning theory. Preliminary searches of the literature identify that most evidence relates to self-examination of testicular, breast, oral or skin cancer, with sporadic primary research associated with other cancer sites/types such as anal cancer.

Increased self-examination for physical signs and symptoms may reduce patient delay and detect cancer earlier and there is existing research at both primary and secondary level in this area. The type(s) of interventions capable of delivering behaviour change such as self-examination are complex, in that they will have many components that interact (14).

Descriptions of interventions have historically been lacking and make it difficult for others to replicate the intervention or allow for meaningful evaluation of the intervention and its individual components. Several tools and reporting structures have been produced to help alleviate this problem including CONSORT, TIDIER and ITAX (15–17). Tate et al. describe how the deconstruction of complex interventions and those that contain behavioural change techniques is like unpacking the 'black box' (18). Deconstructing interventions enables the identification of active ingredients/components and in some cases a determination of the contribution of each component to the overall effectiveness of the intervention.

To the best of the author's knowledge there are no overviews of reviews that bring together the evidence base for self-examination across a range of different cancers whilst deconstructing interventions. Therefore, this umbrella review will address an important gap and provide an up-to-date summary of interventions, their components and indication of effectiveness alongside summarising recommendations for further research/development.

Methods/design

This review has been informed by the PRISMA-P checklist (detailed in additional file 1) for systematic reviews and the JBI methodology for umbrella reviews (19, 20).

Aim: This systematic umbrella review will assess the evidence base surrounding self-examination programmes focused on early detection of cancer.

The review question is: What are the components of self-examination programmes for early detection of cancer and are they effective in bringing about actions that could lead to early detection of cancer in post pubescent people.

Inclusion criteria

The population of interest is post pubescent people without limitation.

The Phenomena of interest is self-examination programmes or interventions focused on the early detection of cancer.

The context will be in community settings but with no limitations on geographical locations or cultural influences.

Objectives:

- To identify effective self-examination interventions as measured by effect on survival.
- To identify the components of existing interventions and summarise these using Intervention Taxonomy (ITAX) as a framework (17).
- To identify and group components into the following categories: component of effective intervention; component of intervention with unclear effect; component of ineffective intervention component
- To identify, code and summarise the behavioural change techniques included in existing interventions in each category using Behaviour Change Technique Taxonomy version 1 (BCTTV1) (21).
- Identify any harms or adverse events associated with self-examination interventions/programmes.
- Identify and group recommendations from included reviews for further research.

Search Strategy

A search strategy for each electronic database will be developed. Additional file 2 presents the search strategy for MEDLINE (OVID) and this will be mirrored in the other databases. Adaptions for each database will be made but the key words and trunks will remain the same. Filters developed by the Scottish Intercollegiate Guidelines Network will be applied to the following databases to select systematic reviews only: MEDLINE (OVID) and CINAHL. The filter published by NIH National Library of Medicine for PubMed and updated in 2018 will be used for that database (22). The Cochrane database already has a

built-in filter separating trials and reviews in the search results. Prospero only hold details for systematic reviews.

Data management/ Selection process

Following application of the search strategy to all stated databases, references will be imported to Endnote software and duplicate titles removed. Two independent reviewers will then screen titles independently and in duplicate, the same two reviewers will apply eligibility criteria to abstracts of screened studies and then to full papers. If there are differences between the reviewers, this will be resolved by discussion in the first instance with any remaining dispute decided by inclusion of a further third independent reviewer.

Taxonomy for intervention deconstruction

The Intervention Taxonomy (ITAX) as described by Schulz et al will be used to deconstruct interventions (17). As discussed in the introduction other frameworks and tools are available such as TIDIER that has been designed as an extension of the COSORT statement with more focus on randomised controlled trials (23, 24). For this umbrella review ITAX provides the best utility for meeting the stated objectives whereby the dimensions described within the taxonomy will enable sufficient data extraction from both randomised and non-randomised study designs to inform future development of community-based interventions.

Further to the use of ITAX, BCTTV1 will be used to code any behavioural change techniques described (21). BCTTV1 provides an internationally agreed and recognised coding system.

Study inclusion and exclusion criteria are presented in Table 1.

Table 1: Study eligibility criteria

<i>Inclusion criteria</i>	<i>Exclusion criteria</i>
<ul style="list-style-type: none">· Systematic reviews summarising evidence from observational or experimental study designs will be included.· Reviews published since 1990.· Reviews published in any language.· Participants that are post pubescent· Any community setting	<ul style="list-style-type: none">· Papers that are not systematic reviews· Reviews that include theories only· Reviews that rely on expert opinion· Abstract only available· Protocol only available

Information Sources

Electronic databases: CINAHL, MEDLINE (OVID), PubMed, Cochrane, Prospero.

Grey: OpenGrey

Hand searching of reference list in included studies.

Data collection process/Data Items

Two data extraction templates, presented in Additional file 3, have been developed a priori using the JBI baseline criteria with additional variables set by the review authors. Data extraction tables will be piloted prior to the full review, with amendments made as appropriate. The first data extraction table focuses on review characteristics and will extract the following information: Title, author, citation, funding source, aim, year, study designs included, cancer type, population, intervention description (reported using ITAX), Behavioural Change Techniques identified (coded using BCTTV1), Comparator, Outcomes, quality assessment tools used, Patient/public involvement in design/planning, Type of analysis/synthesis. The second data extraction table will extract findings and include quality assessment of the systematic reviews capturing the following information: number of included studies and sample size, geographic locations of included studies, date range of search, adverse events, review conclusions on interventions, AMSTAR-2 risk grading, review recommendations for further research and Umbrella review authors comments. Two reviewers from the authorship will carry out data extraction independently

Quality Assessment and Metabias

AMSTAR-2 will be applied to each of the included systematic reviews to assess quality and risk of bias (25). The tool has been designed to be applied to both randomised and non-randomised study designs assessing healthcare interventions. AMSTAR-2 is an updated version of the original tool and takes into account learning from over a decade of use of AMSTAR. Some of the original features of AMSTAR have been retained or modified with further changes providing a more rounded and detailed assessment of risk of bias. Two reviewers will apply the tool independently. Any disagreement will be decided by discussion with arbitration by a third reviewer from the authorship as required.

Data synthesis

Narrative synthesis will be conducted by filtering interventions/programmes into effective, ineffective, and unclear effectiveness. Effectiveness will be defined where an improvement in survival/mortality rate is demonstrated, with ineffective as the converse or showing no difference. When effectiveness data is not available interventions will be classed as having unclear effect. Intervention components will be described and summarised using the domains within ITAX. Where the use of a behavioural change technique is identified or described within ITAX domains these will be coded and grouped in a separate table summarising the BCTs used. Synthesis will also explore the impact of the time period the intervention was developed/delivered, the geographic area and the target cancer type on the intervention

components or effectiveness rating. Recommendations from included reviews of areas of further research will be analysed, grouped and presented.

Discussion/conclusion

The output from this umbrella review will aid researchers, public health practitioners, charitable organisations and health bodies in taking an evidence-based approach to future or further development of self-examination interventions by systematically searching, summarising and presenting the existing evidence base. The overview will also identify gaps in the evidence base enabling researchers to take a more targeted approach to future research in this area.

Abbreviations

NIH	National Institutes of Health
AMSTAR	Assessing the methodological quality of systematic reviews
AMSTAR-2	Assessing the methodological quality of systematic reviews version 2
BCTTV1	Behavioural Change Techniques Taxonomy Version 1
CINHAL	The Cumulative Index to Nursing and Allied Health Literature
CONSORT	Consolidated standards for reporting trials
ITAX	Intervention Taxonomy
PRISMA-P	Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols
TIDIER	Template for Intervention Description and Replication

Declarations

Ethics approval and consent to participate

Not applicable

Consent for publication

Not applicable

Availability of data and materials

Not applicable

Competing interests

NMG holds the voluntary position of trustee with the charity 'Let's talk about mouth cancer SC045100' that promotes mouth self-examination. No other conflicts of interest or competing interests declared.

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Authors' contributions

NMG is the Principal Investigator and has contributed to all aspects of development of this research. HC, LY, DC and JC contributed to the study design, drafting of the protocol and reviewed the final manuscript. SMG contributed to the search strategy development and reviewed the final manuscript.

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Professor Ruth Freeman, University of Dundee sadly died in September 2021. Ruth contributed to the study design and early draft of this protocol.

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Supplementary Files

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- [Additionalfile2examplesearchstrategy.docx](#)
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