

Nurses' interventions to promote cancer patient engagement and related outcomes: a systematic review and meta-analysis protocol

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Abstract. *Background and aim of the work.* Due to the ageing of cancer patients, new approaches that require a more active participation in the self-management of cancer treatment at home are needed. Nurses are strategic in improving the patient's engagement capability in this regard. Knowing which interventions are more effective for the promotion of patient engagement could be useful to improve the effectiveness of the care provided. Therefore, this study aims to systematically review nursing interventions or programs that promote patient engagement in oncological nursing care and summarizing the main evidence related to their impact on relevant clinical and psychosocial outcomes. *Method.* This is a systematic review and meta-analysis protocol based on Cochrane Handbook for the systematic review of interventions. We will search the most important electronic databases (PUBMED, CINAHL, EMBASE, SCOPUS, ISI Web of Science, Cochrane library) to find out which patient engagement interventions (active adult patient involvement) are implemented in oncological settings and understand what is the effectiveness of these interventions on the outcomes reported in the literature. The GRADE methodology will be used to synthesize the evidence. If possible, also a meta-analysis will be performed. We registered the study protocol on the PROSPERO database (N° CRD42020146189). *Discussion and Conclusion.* To our knowledge, this is the first systematic review to address this clinical question in the field of oncology. This review will offer health professionals indications on the most frequently adopted patient engagement interventions and verify their clinical effectiveness. Furthermore, any gaps in the scientific literature will be highlighted. (www.actabiomedica.it)

Key words: patient engagement, nurse, oncology, randomized control trials, non-randomized control trials, systematic review

Background and aim of the work

The cancer burden in the forty countries of the European Region is expected to increase from around 3.6 million cases and 1.8 million deaths in 2015 to 4.3 million cases and 2.3 million deaths in 2035, almost entirely due to the ageing and growth of the population (1). Further increases are also likely to occur

with the changing prevalence of exposure to “modern” risk factors, especially tobacco, alcohol, unhealthy diet, obesity, and sedentary lifestyles. The changes will not be evenly spread throughout Europe, with variations that depend on the prevalence of risk factors, demographic changes and the level of development of the health service screening and therapeutic options, among other parameters.

In Switzerland, cancer causes 9,000 deaths among men and 7,000 among women every year. In other words, 30% of the total deaths in men and 23% in women are due to cancer. In men, 22% of cancer deaths are due to lung cancer, 15% to prostate cancer, and 10% to colorectal cancer. In women, breast cancer is responsible for 19% of the deaths, lung cancer for 15% and colorectal cancer for 10%. In children, cancer deaths are mostly due to leukaemia and brain tumours(2).

To guarantee health system sustainability there is the need to adopt innovative organizational models and paradigms of care with a renewed focus on the promotion of an effective partnership with patients/consumers (3,4), which is a predictor of patient adherence and compliance to treatment (5–7).

In this regard, patient engagement in cancer care is gaining more and more attention (8,9) and is becoming a requirement for the everyday practices of health care organizations to address the aforementioned challenges (10–13).

Patient engagement has been suggested as a strategy to improve the effectiveness and efficiency of health care systems. The concept of patient engagement was drawn up in the USA about a decade ago. This concept was based on the idea that the “individual recipient of care” should be actively engaged across the planning and delivery phases of the health care services. Consequently, patient engagement was soon approved by policy makers and health care managers (14). Therefore, patients not only need to be “put at the centre” of medical actions in terms of consideration of their needs and expectations of care, but should also be seen as a key stakeholder that actively contributes to the successful accomplishment of the health care organization’s mission and actions.

Patient engagement involves taking a further step towards a truly interactive partnership between health care recipients and health care providers, where patients are considered as one of the main protagonists of the management of the health care process in which they are directly involved (14).

Finally, patient engagement research has shown the impact of involving people in their healthcare pathway on relevant clinical, psychosocial and economic outcomes (15–18).

According to the First Consensus Conference on Patient Engagement (10,19), health professionals – and in particular nurses – are the key catalysers of a patient engagement revolution, since they are in the frontline with patients in managing the healthcare process (20,21). Putting patients at the centre of the care pathway is a key element of the nurses’ professional values and scientific research, therefore nurses play a strategic role in promoting patient engagement (22–24).

However, to the best of our knowledge, no literature reviews have been conducted to date on nurses’ interventions aimed at promoting patient engagement in oncology settings. The purpose of this study is to systematically review nursing interventions or programs aimed at promoting patient engagement in cancer nursing care and at mapping the main evidence regarding their impact on relevant clinical and psychosocial outcomes.

Research questions

1. What nursing engagement interventions (active adult patient involvement) have been implemented in oncology settings?
2. What clinical and psychosocial outcomes related to these interventions have been described till now?
3. What is the effectiveness of these interventions on the outcomes considered?

Methods

This is a systematic review protocol and it was drafted according to the Preferred Reporting Items for Systematic Review and meta-analysis protocols (PRISMA-P) check-list (25). We registered the review protocol in the PROSPERO database (Registration number: CRD42020146189).

PICOS

- **P:** Cancer Patients In General (No Specific Diagnosis)
- **I:** Nursing Engagement Interventions
- **C:** Routine Care
- **O:** Improvement of Clinical and Psychosocial Outcomes

- **S:** Randomized Controlled Trials, Quasi Experimental Studies (Non-Randomized Controlled Trials)

Study inclusion and exclusion criteria

All studies considering nursing interventions for the promotion of patient engagement in oncology settings shall be included. To increase the likelihood of retrieving papers related to the research questions, studies reporting concepts similar to patient engagement (i.e. patient empowerment, patient activation, patient involvement, patient participation) shall be included.

We shall try to identify the principal outcomes of patient engagement described in the literature to date, in the field of clinical oncology nursing, to draw a map and evaluate their impact from a clinical and psychosocial point of view.

With regard to the designs of the included studies, since our purpose is to provide an answer to a therapeutic question, we shall include Randomized Controlled Trials. To gain a more comprehensive understanding of what has been studied till now, also non-randomized controlled trials will be included, based on the Cochrane manual for systematic reviews (26).

The type of cancer diagnosis will not be an element of exclusion and all studies involving cancer patients shall be included. We shall include articles written in English, French, Spanish and Italian.

Letters to the editor, case reports, case series, comments and other similar types of papers shall not be included. Also studies involving children will be excluded, given the particular needs of this type of population.

Electronic databases

The following electronic databases will be searched: PUBMED; CINAHL; EMBASE; SCOPUS; ISI Web of Science; Cochrane library.

To retrieve studies not published in peer-reviewed journals and avoid publication bias, also grey literature will be searched through Google Scholar.

Search strategy

The following search terms will be used: (“patient engagement” OR “consumer engagement” OR “patient empowerment” or “consumer empowerment” OR “patient activation” or “consumer activation”, OR “patient involvement” or “consumer involvement” OR “patient participation” OR “consumer participation”) AND (nurs* OR “oncology nurs*”) AND (neoplasm OR tumor OR cancer OR neoplasia OR oncol*).

Where possible, the electronic database Thesaurus and MeSH terms will be used, to refine the string of search terms.

The list of references found in the papers will be uploaded onto Mendeley to remove duplicates. Two researchers will independently search the electronic databases and screen the titles and abstracts. Other studies will be retrieved by scanning the reference lists of the included papers. If necessary, we will contact the authors of a paper to obtain any important missing information.

The review will be conducted on papers published in the last 15 years (2005-2020).

Study selection

The selection of the papers to be included will be performed by two researchers independently, by reading the title and abstracts. To avoid duplication, because of multiple papers derived from the same dataset, articles with the same author name, conducted in the same context and period, will be checked.

The papers that meet the inclusion criteria will be evaluated independently by two researchers and the decision to include or exclude a paper will be made jointly following a discussion.

If no agreement is reached, a third researcher will be consulted. The study selection process will be presented using the PRISMA statement flow chart.

Data extraction

The data of the included studies will be extracted by two researchers independently in a systematic way.

The following data will be extracted from the studies: name of the first author and date of publication,

country where the study was carried out, objective/research question/hypothesis of the study, method used (specifying the study design, the data collection process, sample size calculation, if it is a blinded study, the process of randomization and recruitment, if the authors performed an Intention-to-treat analysis, description of the experimental intervention, description of the control intervention, description of the outcomes evaluated, main results (both punctual data and the 95% confidence interval of the main outcome will be reported, if these are available in the included studies)), and main conclusions. Data extraction will be summarized in a table.

Quality appraisal of the included studies

The quality of the included studies will be assessed independently by two researchers. In case of disagreement a third researcher will be consulted. For the quality appraisal of the Randomized Controlled Trials, we will use the revised version of the “Cochrane Risk of Bias Tool for Randomized Controlled Trials” (RoB 2.0) (27).

This tool evaluates the range of possible biases of RCTs, such as selection bias, concealment bias, selective reporting, detection bias, and attrition bias. The studies can be classified from high to low risk of bias or uncertain. We will report the quality assessment of the studies in a table to compare all the studies included in the systematic review.

For the Non-Randomized Controlled Trials (NRCTs) we will use the Cochrane tool Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I tool) (28).

Statistical analysis

Tables will be created to summarize the data of the included studies and highlight their characteristics in the light of the purpose of this review. Following data extraction, the research team will evaluate the possibility of performing also a meta-analysis. Heterogeneity across studies will be evaluated using Cochran's Q and Higgins's I^2 statistics. A Chi square $< .10$ or an $I^2 > 50\%$ will be classified as a high level of heterogeneity.

Synthesis of the results

An integrated analysis of the included studies will be performed to assess the impact of patient engagement interventions on the outcomes considered, providing, if possible, the confidence interval to estimate the effect size.

Sensitivity analysis

If possible, a sensitivity analysis will be performed to evaluate the influence of each study on the effect of the patient engagement intervention in favouring the outcomes considered, excluding one study at a time to see how the effect changes.

Evidence synthesis

The quality of evidence will be assessed with the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system (29), which uses a sequential evaluation of the quality of evidence and assesses also the cost-benefit ratio, thus determining the strength of the recommendation.

Validity and reliability

The systematic review will be conducted according to the Cochrane Handbook for Systematic Reviews of Interventions (26). All the steps of the systematic review, such as searching the electronic databases, study selection and appraisal, will be conducted independently by two researchers and a third researcher will be consulted in case of disagreement. The GRADE methodology will be used to synthesize the evidence.

Discussion

This study reports the research protocol of a systematic review aimed at identifying which patient engagement nursing interventions are implemented in oncology settings, as well as what clinical and / or psychosocial outcomes the interventions have produced so far.

Moreover, if the studies meet the criteria of quality and homogeneity, the present revision shall aim to investigate – through a meta-analytical approach – the effectiveness of the patient engagement interventions.

To the best of our knowledge, this is the first systematic review that addressed this clinical question in the field of oncology.

This review will produce indications regarding the most common patient engagement nursing interventions and enable to evaluate their clinical effectiveness. Furthermore, any gaps in the scientific literature will be highlighted.

Limitations

It is very likely that few Randomized Controlled Trials have been conducted to date on this particular research question. Therefore, it is possible that not much evidence will be available.

Conclusion

To ensure the sustainability of health systems it is necessary to adopt innovative organizational care models and paradigms with a renewed focus on the promotion of an effective partnership with patients/consumers. Particularly in oncological settings, new approaches are needed due to the aging of cancer patients, which require a more active participation in their health management, and nurses can play a key role in improving patient engagement capability. Knowing which interventions are more effective in promoting patient engagement could be useful to improve the quality of care.

Ethical considerations

Since this was a systematic review, no formal approval from the ethics committee was required.

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Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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