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Protocol for a pilot and feasibility study evaluating a complex nurse-led patient education intervention to promote cancer patient engagement in healthy lifestyle (O-PHE programme)

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ABSTRACT

Introduction Literature suggests that patient engagement in healthy lifestyle is of crucial importance in ensuring a more effective management of side effects of cancer therapies and better quality of life for patients. While many studies describe educational interventions to promote healthy lifestyles, few are focused on promoting active patient engagement in this field. This protocol paper outlines a study to determine the feasibility of a complex nurse-led patient education intervention aimed to promote cancer patient engagement in a healthy lifestyle.

Method and analysis This is a randomised pilot and feasibility study. Research nurses will recruit 40 adult patients newly diagnosed with cancer. Consenting participants will be randomised to undergo the patient engagement in healthy lifestyle intervention or the control group by means of a four-block randomisation procedure. The intervention will be delivered by a clinical nurse trained in patient engagement strategies. The primary outcome will be a description of study feasibility (recruitment and retention rates, protocol adherence and stakeholder acceptability). Secondary outcomes include changes between and within groups in healthy lifestyle behaviours (ie, increase in healthy diet, smoke cessation or reduction, increase in physical activity), in quality-of-life rates after the intervention, in patient engagement levels, in the perception of the quality of care, in nutritional status; the number of recurrences or the onset of new cancer diagnosis; the number of hospitalization.

Ethics and dissemination The study protocol has been approved by the Canton Ticino Ethical Committee (Protocol ID: 2020-02477 TI). The results will be published in peer-reviewed journals and will be presented at national and international congresses. Finally, patients' organisations, such as the Swiss Cancer League, will be involved in the dissemination process. This study will inform the decision to proceed with a randomised controlled trial to assess the effect of this intervention.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The intervention is based on a solid theoretical background and evidence-based practice guidelines.
⇒ The outcomes to be assessed by this study are relevant to people receiving cancer care, clinicians and policy makers.
⇒ Patients will be actively involved in the revision of the study procedure, to modify the intervention based on their suggestions.
⇒ A potential limitation is that study participants will be recruited from one oncology outpatient service provider and is not focused on specific cancer diagnosis which means findings may not be generalisable to all people receiving cancer care.

INTRODUCTION

Patients with cancer, especially in the postdiagnosis phase, can often feel disoriented and unwilling to actively take care of their health.[1] Fisher *et al*[2] state that active patient participation and engagement are necessary steps towards an effective and more sustainable management of health services.

A study conducted by Hibbard and Greene[3] on a sample of 33 000 patients suffering from chronic disease showed that a high level of patient engagement could reduce healthcare costs by up to 21%.

Promoting patient engagement also means increasing patients' safety and quality of life. This was revealed by Weingart *et al*[4] in a study conducted on more than 2000 patients within a hospital setting, where a higher level of patient engagement was associated with a 50% reduction in postdischarge adverse events.

With reference to patients with cancer, scientific evidence suggests that patient

engagement in the treatment process ensures an overall improvement in clinical outcomes.[5–8] Several studies have shown that patients with cancer who have been actively involved in their treatment plans are more satisfied with the treatment received[5] and more likely to adopt preventive screening and check-up behaviours.[9 10] Finally, patients with higher levels of patient engagement in their healthcare reported a better quality of physical and mental health.[5 6] A recent study noted that increased patient engagement in disease management can also positively influence the ability to maintain good work performance and psychological well-being in daily life.[11] Furthermore, the literature has shown how actions and initiatives to actively involve patients in the management of their care are a key strategy to make the healthcare system fairer, more effective and sustainable.[12 13]

Literature suggests that promoting cancer patient engagement in healthy lifestyles, such as proper nutrition, physical activity and abstention from smoking, is of crucial importance in ensuring better management of side effects of therapies, better quality of life, better functional recovery.[14] The World Cancer Research Found/American Institute for Cancer Research (WCRF/AICR), points out that for some cancer diagnosis, such as breast cancer, these behaviours can help control tumour growth during different stages of the disease, reducing the risk of recurrence.[14]

The nursing profession has a long history of focusing its academic and professional development on establishing active collaboration with patients, promoting their self-care and autonomy in order to enhance patients' residual capacities.[15–17] For these reasons, the nursing profession is particularly appropriate to lead health education interventions among the care team and in collaboration with other healthcare practitioners.[18]

Objectives

According to these premises, the overarching aim of this pilot and feasibility study is to determine the feasibility of a complex nurse-led intervention to promote patient engagement in healthy lifestyle for people receiving cancer care. A quantitative and qualitative feasibility assessment will be undertaken to inform the decision to proceed with a randomised controlled trial (RCT) to assess the effect of this intervention.

Primary objectives

The primary objectives of the pilot and feasibility study are as follows:

1. Optimise the design and delivery of the intervention in partnership with patients and healthcare professionals (HCPs) to maximise acceptability, effectiveness and long-term uptake.
2. Assess whether recruitment, engagement with the intervention and retention to the trial outcomes are sufficient to allow the trial to progress and provide a definitive answer on effectiveness.
3. Explore, qualitatively, the acceptability of the recruitment processes, assessments, intervention delivery and secondary outcome measures with key stakeholders (patients and clinicians).
4. Conduct a process analysis in line with Medical Research Council (MRC) guidelines for complex interventions to determine barriers and facilitators to implementation.

Secondary objectives

The secondary objectives are:

To estimate the short-term and long-term impact on patient outcomes and health service costs by determining whether there are changes between and within groups, at 1, 3, 6, 12, 24 months follow-ups, in:

- Healthy lifestyle behaviours (ie, increase in healthy diet, smoke cessation or reduction, increase in physical activity).
- Quality-of-life rates.
- Patient engagement.
- Quality of care perception.
- Nutritional status.
- The number of recurrences or the onset of new cancer diagnosis.
- The number of hospitalisations.

METHODS AND ANALYSIS

Study design

The development of this pilot study protocol was informed by the guidelines to develop complex interventions provided by the Medical Research Framework (MRC).[19] In particular, the pilot will follow the first two phases described by the MRC framework (figure 1).

For this study, we will use a non-blinded RCT design with an intervention group and a control group (1:1 ratio), to determine the feasibility of a complex nurse-led intervention aimed at promoting patient engagement in healthy lifestyle for people receiving cancer care. Based on the pilot study, an actual clinical trial will be designed, including the definition of the necessary sample size and considering the possibility of implementation at a multicentre level.

Participants and setting

All patients aged 18 years or older with new oncological diagnosis, and under the care of the Oncology Institute of Southern Switzerland (IOSI) outpatient clinic in Mendrisio will be screened for eligibility and invited to participate by study researchers. Only eligible patients will be invited to participate in the study. Written informed consent will be obtained from the patient prior to inclusion in the study.

Eligibility criteria

Participants identified at the IOSI outpatient clinics in Mendrisio will be eligible for the study if they fulfil the following criteria:

- Inclusion criteria: age ≥18 years, newly diagnosed with cancer, able to read and understand the Italian

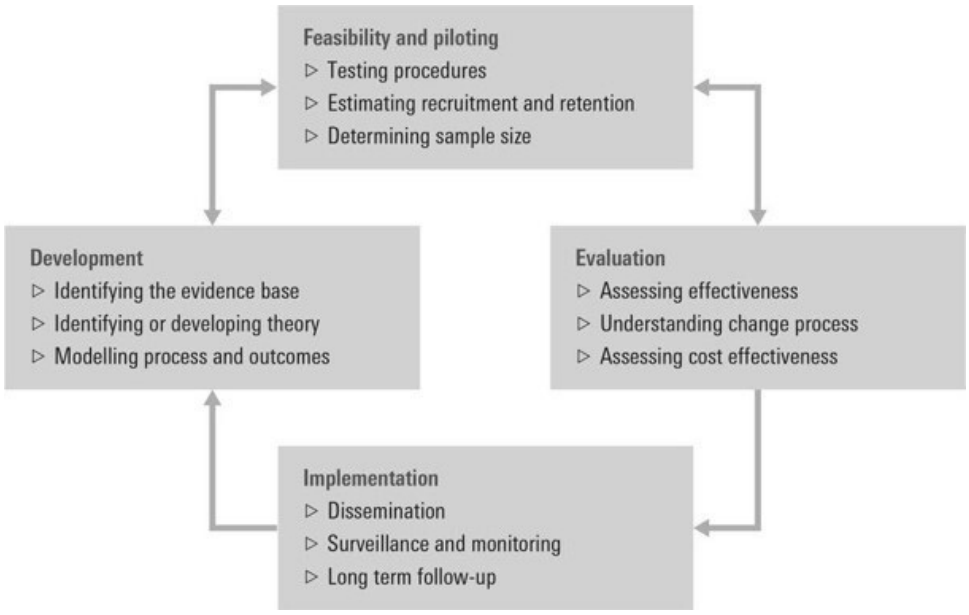

Figure 1 Key elements of the development and evaluation process according to the Medical Research Council framework for the development of a complex intervention (adapted from: Craig *et al*[19]).

language and willing to provide written informed consent.

- Exclusion criteria: patients with mental health disorders, cognitive deficits (Short Blessed Test ≥10), patients with severe malnutrition, patients in artificial nutrition (enteral or parenteral), advanced oncological pathology, life expectancy less than 6 months, patients who must undergo major surgery.

Sample and randomisation

For the pilot study, according to other studies,[20 21] we will involve 20 patients in the intervention group and 20 patients in the control group. This sample size is considered sufficient for the purpose of collecting feasibility data to improve the intervention, testing the planned recruitment method and assessing the acceptability/readability of the outcome measures. All patients who agree to participate will be randomised to either the intervention or the control group by means of a four-block randomisation procedure. To keep the randomisation sequence hidden, opaque sealed envelopes will be used.

Intervention: the 'Oncology Patient Health Engagement (OPHE) programme'

Participants randomised to the treatment condition will undergo the OPHE programme. The intervention has been informed by the theoretical lenses offered by the Patient Health Engagement Model (PHE).[22] According to the theoretical framework provided by the PHE model, patient engagement is a developmental process that can be described as the recovered patients' ability to have life projectuality and goal directedness—even if living with a disease. It implies patients' changes at cognitive, emotional and behavioural domains. In this process, patients go through four experiential phases (namely: blackout, arousal, adhesion and eudaimonic project). These phases are explained in more details in some seminal articles.[17 22–26] The unachieved synergy among the different subjective dimensions (cognitive, emotional, behavioural) at each stage of the process may obstacle patients' ability to engage in their care. The PHE model may be used as a psychological framework not only to assess the engagement phase of patients, but also to detect their (unmet) needs and expectations towards their own care process. In particular, specific needs of support are referrable to each PHE phase. The PHE*in*ACTION educational intervention protocol—that oriented the design of the present intervention with specific adaptation to the scope and setting of this project—has been developed specifically to support patients in their psychological journey of engagement.[27]Similarly to the PHE*in*ACTION intervention,[27–29] an intervention booklet has been developed. Materials have been structured into three main sections according to the patient engagement domains described by the PHE model. This is aimed at providing a guide for the nurse–patient encounters to define the personalised contents of the patient engagement intervention. The booklet sections and specific tasks related to each patient engagement domain and according to the four phases of patient engagement are as follows:

Part 1: me and my illness experience (i.e., emotional processing domain)

The tools in this section of the booklet aim to encourage patients to adapt to their new health status, to make them able to elaborate and reflect on their illness experience and to support them to change their life habits. For the individual in 'blackout' phase, the exercise proposed is a task of expressive writing aimed at favouring a first elaboration and coping with the disease and the lifestyle changes he/she is implementing. The person in the 'arousal' phase has the task to write a weekly diary to

highlight the main positive things and thoughts about the changes he/she is implementing. Also, for the patient in the 'adhesion phase', the task aims at focusing on sources of positive thinking through mapping and visualising situations, places or people that make him feel good and support him in changing her/his lifestyle. Finally, to the person in the 'eudaimonic project phase', we will propose a positive psychology exercise, which involves identifying three individual strengths to be used in daily life to maintain healthy lifestyle behaviours.

Part 2: information about healthy lifestyles in cancer care (i.e., cognitive processing domain)

This section aims to support the process of managing information about healthy lifestyles, guiding and supporting the patient during the change through correct information and consolidation of knowledge about the contents of the educational intervention (healthy nutrition, physical activity and smoking cessation).

Particularly, for the patient in 'blackout', an elicitation exercise on what the patient knows about the impact of healthy behaviours on the disease is required. The task for the person in the arousal position is a preparation for the next therapeutic education meeting on the adoption of healthy lifestyles, with the setting up of specific questions, or curiosities on the topics discussed (physical activity, healthy nutrition); this exercise allows the person to organise his/her thoughts and evaluate his/her knowledge. The third exercise is called the information briefcase and is dedicated to the individual in the position of adhesion; it consists of a series of proposals to better manage information and knowledge such as a diary in which to write down vital parameters, a logbook on physical activity, etc. To the person in the eudaimonic project phase, the mapping of information sources such as magazines, websites, and patients' associations is proposed, which can increase the information on the issues addressed in the educational intervention, sharing materials with the nurse.

Part 3: effectively managing the changes in lifestyle habits (i.e., behavioural processing domain)

This section is aimed to align with patients on what changes and actions the patient can concretely and realistically implement regarding physical activity, proper nutrition and abstaining from smoking.

The first exercise for the person in blackout involves listing the areas for action such as diet and nutrition, physical activity, smoking and identifying the behaviours to be implemented; then there is a mapping of the informal network, which supports the management of actions. For people in the arousal phase, there is a self-assessment exercise of action skills and definition of areas of need. For persons in the phase of adhesion, there is a test of the implementation of an action plan. The plan defines actions, places, people and times for adopting healthy lifestyles. The last exercise, foreseen in the eudaimonic project phase, is a test of prefiguring potential obstacles for the realisation of the action plan. The exercise aims at encouraging the maintenance of the acquired behavioural changes.

For example, if the patient is in the blackout phase of engagement the nurse will propose the following activities linked to the three main domains described by the PHE model:

- Emotional processing domain: Expressive writing exercise on the experience of illness and lifestyle changes.
- Cognitive processing domain: Exercise in eliciting knowledge about diseases and healthy lifestyles through drawing/writing.
- Behavioural processing domain: Mapping of actions required to improve lifestyles and informal support network.

The intervention will consist of an initial visit of 1 hour (T0), followed by a telephone follow-up at 2 weeks and three other meetings (the first at 1 month from T0 (T1), the second at 3 months (T2) and the third at 6 months (T3). Further follow-up visits will take place at 12 and 24 months after T0 (the actual trial will begin within 1 year of the start of the pilot study, when it is very likely that any critical issues in the intervention have already been verified. A detailed description of the intervention will be reported, as suggested by the latest indications of clinical research, through the Template for Intervention Description and Replication (TIDieR) check list.[30] To guide the intervention, the booklet created for the complex PHE in action intervention and adapted for the oncology context will be used. The booklet will also serve to aid the patient to plan his/her activities and aims during the pathway.

The contents of the educational intervention with respect to proper nutrition, proposed physical activity and abstention from smoking will be individualised according to the patient's personal characteristics and preferences, also considering his or her level of engagement. The information content that will be provided to patients will derive from existing information material, appropriately selected, as for example, Smart food IEO guidelines, WCRF/AICR[14] recommendations and Swiss Cancer League materials.

Two oncology specialist nurses with a consolidated experience in cancer care, who have been trained on patient engagement theory and strategies, will deliver the complex nurse-led intervention. The protocol is simple and structured, and may be self-administered by the patient, although with the support and supervision of the intervention provider.

Control group

As carried out in other studies,[31–35] the control intervention providing standard of care, will consist of providing people who will be randomised to this group, information materials about healthy lifestyle, but they will not be involved in the educational intervention provided by the nurse. Also, in the control group all the variables identified for the experimental group will be monitored (ie,

Table 1 Endpoints and assessment tools

Endpoints	Assessment tools
Lifestyles (food habits, physical activity, smoking, sleep)	The primary outcome will be measured by means of the WCRF/AICR score[37]; Step watch will be used for monitoring physical activities parameters.
Patient engagement	Patient Health Engagement Scale (PHE-s)[22]
Quality of life	EQ-5D-3L[38]
Anthropometric parameters, nutritional status; clinical exams	Body mass index, abdominal circumference, weight gain or loss, cholesterol, glycated haemoglobin
Perception of the quality of care received	Healthcare Climate Questionnaire[39]
Recurrences or the onset of new cancers, hospitalisations	Patients' clinical records
Perception of the intervention (feasibility of the intervention contents and procedures)	Semi-structured interviews with patients and clinicians

EQ-5D-3L, EuroQol-5 Dimension-3 Level; WCRF/AICR, World Cancer Research Found/American Institute for Cancer Research.

the level of engagement, lifestyle changes, nutritional parameters, quality of life, recurrences or the onset of new cancers, number of hospitalisations).

Intervention adherence

Study coordinators will monitor and encourage participants' adherence to the intervention protocol. All missed or incomplete intervention sessions will be documented.

Intervention providers' training

Intervention administrators will undergo training in the treatment and control protocols, and each will be responsible for providing both treatments. Training for the intervention protocol will consist of three 90 min sessions, while control protocol training will include one 60 min session. A training manual for intervention and control conditions will also be provided to support the administrators. Training materials can be obtained by contacting the study corresponding author. The two nurses who will deliver the intervention have attended this training.

Concomitant care

Patients enrolled in the trial will continue to receive and undergo all usual clinical care activities. Changes in clinical care or status during the study that could influence outcomes will be documented.

Data collection

For each outcome, a specific validated tool for data collection will be adopted as reported in table 1.

Participants' demographic data (ie, gender, age, education, profession, (previous profession if retired), oncological disease, possible comorbidities, oncological therapy, other therapies) will also be collected as baseline measures.

Participants (both involved in the intervention and control groups) will be invited to complete paper and pencil questionnaires following the time schedule which is reported in table 2.

Process evaluation

The process evaluation will follow the MRC guidelines for evaluating the implementation of complex interventions. It will explore the fidelity and implementation of intervention, and make recommendations for adaptations. It will also examine the potential mechanisms underlying

Table 2 Data collection plan and follow-up

Assessment tool	T0=first meeting	Two weeks telephone Follow-up	T1=second meeting after 1 month	T2=third meeting after 3 months	T3=fourth meeting after 6 months	12 months follow-up	24 months follow-up
Demographic data	X Y						
Lifestyle, WCRF score, Step watch	X Y		X Y	X Y	X Y	X Y	X Y
QoL EuroQoL EQ-5D-3L	X Y		X Y	X Y	X Y	X Y	X Y
Patient Health Engagement	X Y		X Y	X Y	X Y	X Y	X Y
Nutritional status	X Y		X Y	X Y	X Y	X Y	X Y
Follow-up data		X				X Y	X Y
Healthcare Climate Questionnaire					XY		
Cancer recurrence (yes/no)						X Y	X Y
Rehospitalisations						X Y	X Y
Semistructured interviews to patients receiving the intervention					X		

EQ-5D-3, EuroQol-5 Dimension-3 Level; WCRF, World Cancer Research Found; X, intervention group; Y, control group.

participant behaviour change and probe for unexpected consequences.

Brief qualitative interviews will be conducted face to face with patients undergoing the intervention (target n>5) and clinicians recruiting to the study (n>5). Interview data collected from the process evaluation will be analysed using thematic analysis. Data will be analysed using NVivo to establish themes and subthemes. A mixed-methods approach will be used to integrate quantitative and qualitative data in order to fully explore implementation of the intervention.

Data analysis

SPSS V.26.0 version will be used for statistical analysis. A descriptive analysis of the main variables will be conducted. The nominal variables will be represented in terms of frequency and percentages, and the ordinal or continuous variables, respectively, in terms of medians, quartiles, means and SD. To compare the groups based on the qualitative variables, the χ^2 or Fisher's exact test will be used. The Mann-Whitney U test or t test for unpaired groups will be used to compare the ordinal or continuous variables, respectively, if the distribution is normal. The Kolmogorov-Smirnov normality test will be used to determine the normality of the distributions of the continuous variables. The significance level will be set at $p<0.05$ (two tailed). Power analysis will be conducted to determine sample size, based on the WCRF score, considering an effect size of 0.5, to reach a power of 80%, with an alpha level 0.05 and a two-tailed test.

Data management

All participant information and data will be stored securely on password-protected computers, including participant files, signed consent forms, questionnaires, correspondence, data and medical information collected, and other documents relating to the conduct of the study. Electronic data will be kept on computers at the IOSI, that are located on a secure server which is password protected and backed up daily. Any hard copy data that contains participant information will be filed in a lockable filing cabinet at the IOSI under the responsibility of the principal investigator, and other research staff. Documents containing participant identifiers will be kept separately to data collected, which will be identifiable by unique participants IDs instead. Only approved research team members can access the relevant file locations. Access to the database and passwords will be restricted to the principal investigator, study coordinator and study research assistants. A data monitoring committee is not required as the proposed study poses minimal risk to participants.[36] At the conclusion of the study, study resources and participant information/data will be stored in a secure storage facility for 10 years (from publication). Ethics applications for any future research activities during this time will be applied for as necessary. After this time, any identifiable information will be confidentially disposed of; paper-based documents will be shredded and all electronic files deleted.

Patient and public involvement

The complex nurse-led patient education intervention will be adapted according to continuing consultation of patients, who will be involved in intervention's revision during and at the end of the pilot study. As stated, patients will be interviewed to understand the acceptability of the intervention and its perceived effectiveness to engage patient in healthier life style. The design of the trial and its dissemination will also have been shaped by a cancer patient organisation (i.e., patient and public involvement (PPI) group) in the following ways:

- Reviewing and selecting patient-relevant outcome measures.
- Co-design recruitment procedures.
- Reviewing the intervention contents and structure and providing feedback.
- Giving input for feasibility interview topics and suggesting questions for process evaluation.
- Codesigning lay dissemination materials.

The PPI group primarily participates remotely to allow participation from members who are not local. Face-to-face input occurs at key moments of the protocol design.

Ethics and dissemination

Ethics

The study protocol has been approved by the Canton Ticino Ethical Committee on the 23 December 2020 (Protocol ID: 2020-02477 -TI). Moreover, the medical and nursing directions of the IOSI have officially approved the protocol. A grant request has been submitted to the Fond'Action contre le cancer for the pilot study (results pending).

Dissemination

All data collected from participants will be deidentified and summarised (eg, reporting averages) in disseminating the findings. Trial results will be disseminated to patients with a summary sheet that will outline the trial findings in lay language and patients' associations, such as Swiss Cancer League will be involved in the dissemination through their communication channels (ie, social media, official website…).

Results will be disseminated to HCPs and researchers via publication in an academic journal and presentation at academic conferences.

Study status

Study recruitment started in September 2021, and it is expected to be completed by September 2023.

DISCUSSION

Based on our knowledge, this is the first project in Switzerland that aims to engage the patients in the management of their health, focusing on the adoption of healthy lifestyle, as suggested by the WCRF/AICR guidelines.[14]

The proposed pilot RCT has a number of strengths. The intervention is based on solid theoretical background and evidence-based practice guidelines, and it will guarantee patient and public participation as well as patients will be actively involved in the development and revision of the study procedures. Moreover, the outcomes that will be assessed in this intervention are relevant to people receiving cancer care, clinicians and policy makers. However, there is also some potential limitation related to the fact that the study participants will be recruited from one oncology outpatient service provider and is not focused on specific cancer diagnosis, which means findings may not be generalisable to all people receiving cancer care.

This study will determine the feasibility of a multicomponent complex nurse-led patient education intervention to promote patient engagement in healthy life-style in people cancer care, which will inform the development and implementation of a subsequent RCT, should this be feasible.

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Contributors Study concept and design: LB, CF-S, MCR, AC and SB. Drafting of the manuscript: LB, SB, AT and SL. Critical revision of the manuscript for important intellectual content: LB, CF-S, MCR, AC and SB. Study supervision: DS, LB and SB. All authors read and approved the final manuscript.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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REFERENCES

1 Kübler-Ross E, Kessler D. The five stages of grief. In: *On grief and grieving*. Library of Congress Catalogin in Publication Data, 2009: 7–30.
2 Fisher ES, Shortell SM, Savitz LA. Implementation science: a potential catalyst for delivery system reform. *JAMA* 2016;315:339–40.
3 Hibbard JH, Greene J. What the evidence shows about patient activation: better health outcomes and care experiences; fewer data on costs. *Health Aff* 2013;32:207–14.
4 Weingart SN, Zhu J, Chiappetta L, *et al*. Hospitalized patients' participation and its impact on quality of care and patient safety. *Int J Qual Health Care* 2011;23:269–77.
5 Ashraf AA, Colakoglu S, Nguyen JT, *et al*. Patient involvement in the decision-making process improves satisfaction and quality of life in postmastectomy breast reconstruction. *J Surg Res* 2013;184:665–70.
6 Krouse RS, Grant M, McCorkle R, *et al*. A chronic care ostomy self-management program for cancer survivors. *Psychooncology* 2016;25:574–81.
7 Mosen DM, Schmittdiel J, Hibbard J, *et al*. Is patient activation associated with outcomes of care for adults with chronic conditions? *J Ambul Care Manage* 2007;30:21–9.
8 Stacey D, Samant R, Bennett C. Decision making in oncology: a review of patient decision AIDS to support patient participation. *CA Cancer J Clin* 2008;58:293–304.
9 Katz ML, Fisher JL, Fleming K, *et al*. Patient activation increases colorectal cancer screening rates: a randomized trial among low-income minority patients. *Cancer Epidemiol Biomarkers Prev* 2012;21:45–52.
10 Krist AH, Woolf SH, Johnson RE, *et al*. Patient education on prostate cancer screening and involvement in decision making. *Ann Fam Med* 2007;5:112–9.
11 van Maarschalkerweerd P, Rademakers J, Rijken M. Cancer survivors' activation to self-management and its relationship with participation in paid work and work-related problems. *Psychooncology* 2017;26:1881–7.
12 Hendren S, Griggs JJ, Epstein RM, *et al*. Study protocol: a randomized controlled trial of patient navigation-activation to reduce cancer health disparities. *BMC Cancer* 2010;10:551.
13 Anderson G, Rega ML, Casasanta D, *et al*. The association between patient activation and healthcare resources utilization: a systematic review and meta-analysis. *Public Health* 2022;210:134–41.
14 World Cancer Research Found/American Institute for Cancer Research(WCRF/AIFC). Diet, nutrition, physical activity and cancer: a global perspective, 2018. Available: https://www.wcrf.org/diet-and-cancer/cancer-prevention-recommendations/ [Accessed 16 Mar 2022].
15 Barello S, Graffigna G, Vegni E. Patient engagement as an emerging challenge for healthcare services: mapping the literature. *Nurs Res Pract* 2012;2012:1–7.
16 Lammon CAB, Stanton MP, Blakney JL. Innovative partnerships: the clinical nurse leader role in diverse clinical settings. *J Prof Nurs* 2010;26:258–63.
17 Graffigna G, Barello S, Bonanomi A. The role of patient health engagement model (PHE-model) in affecting patient activation and medication adherence: a structural equation model. *PLoS One* 2017;12:e0179865.
18 Bonetti L, Tolotti A, Anderson G, *et al*. Nursing interventions to promote patient engagement in cancer care: a systematic review. *Int J Nurs Stud* 2022;133:104289.
19 Craig P, Dieppe P, Macintyre S, *et al*. Developing and evaluating complex interventions: the new medical research council guidance. *Int J Nurs Stud* 2013;50:587–92.
20 Hertzog MA. Considerations in determining sample size for pilot studies. *Res Nurs Health* 2008;31:180–91.
21 Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. *J Eval Clin Pract* 2004;10:307–12.
22 Graffigna G, Barello S, Bonanomi A, *et al*. Measuring patient engagement: development and psychometric properties of the patient health engagement (Phe) scale. *Front Psychol* 2015;6:274.
23 Barello S, Graffigna G. Engaging patients to recover life projectuality: an Italian cross-disease framework. *Qual Life Res* 2015;24:1087–96.
24 Graffigna G, Barello S. Patient engagement in healthcare: pathways for effective medical decision making. *Neuropsychol Trends* 2015;17:53–65.
25 Graffigna G, Barello S. Spotlight on the patient health engagement model (Phe model): a psychosocial theory to understand people's meaningful engagement in their own health care. *Patient Prefer Adherence* 2018;12:1261–71.
26 Graffigna G, Barello S, Riva G, *et al*. Italian consensus statement on patient engagement in chronic care: process and outcomes. *Int J Environ Res Public Health* 2020;17. doi:10.3390/ijerph17114167. [Epub ahead of print: 11 Jun 2020].

27 Menichetti J, Graffigna G. "PHE in action": development and modeling of an intervention to improve patient engagement among older adults. *Front Psychol* 2016;7:1405.
28 Menichetti J, Pitacco G, Graffigna G. Exploring the early-stage implementation of a patient engagement support intervention in an integrated-care context-a qualitative study of a participatory process. *J Clin Nurs* 2019;28:997–1009.
29 Menichetti J, Kulla A, Bosio C, *et al*. Impact of a patient engagement support intervention (PHEinAction) on pre-bariatric surgery patients: a qualitative evaluation study. *Psicol DELLA Salut* 2021:117–38.
30 Hoffmann TC, Glasziou PP, Boutron I, *et al*. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014;348:g1687.
31 Kurt G, Akyuz A. Evaluating the effectiveness of interventions on increasing participation in cervical cancer screening. *J Nurs Res* 2019;27:e40.
32 Di Meglio A, Martin E, Crane TE, *et al*. A phase III randomized trial of weight loss to reduce cancer-related fatigue among overweight and obese breast cancer patients: medea study design. *Trials* 2022;23:193.
33 Mak WC, Yin Ching SS. Effect of an education program on knowledge, self-care behavior and handwashing competence on prevention of febrile neutropenia among breast cancer patients receiving doxorubicin and cyclophosphamide in chemotherapy day centre. *Asia Pac J Oncol Nurs* 2015;2:276–88.
34 Peixoto NMDSM, Peixoto TADSM, Pinto CAS, *et al*. Nursing intervention focusing on health promotion behaviors in adult cancer patients: a scoping review. *Rev Esc Enferm USP* 2021;55:e03673.
35 Sheppard VB, Hicks J, Makambi K, *et al*. The feasibility and acceptability of a diet and exercise trial in overweight and obese black breast cancer survivors: the stepping stone study. *Contemp Clin Trials* 2016;46:106–13.
36 Lin JY, Lu Y. Establishing a data monitoring committee for clinical trials. *Shanghai Arch Psychiatry* 2014;26:54–6.
37 Shams-White MM, Brockton NT, Mitrou P, *et al*. Operationalizing the 2018 world cancer research Fund/American Institute for cancer research (WCRF/AICR) cancer prevention recommendations: a standardized scoring system. *Nutrients* 2019;11. doi:10.3390/nu11071572. [Epub ahead of print: 12 Jul 2019].
38 EuroQoL group. EQ-5D-3L questionnaire; 1990.
39 Williams GC, Deci EL. The importance of supporting autonomy in medical education. *Ann Intern Med* 1998;129:303–8.