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Carson KV, Labiszewski NA, Brinn MP, Esterman AJ, Peters M, Wood-Baker R, Smith BJ

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[Intervention Protocol]

Consumer guidelines for chronic disease management

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the effects of consumer guidelines for people with chronic illnesses, on health outcomes.

BACKGROUND

Description of the condition

Chronic illnesses are characterised by their long duration and generally slow progression (WHO 2012). They are not limited to non-communicable diseases; further, public health specialists increasingly view some diseases that were formerly considered to be terminal (such as HIV/AIDS and some cancers) as chronic illnesses. These conditions require long-term, ongoing and comprehensive health services similar to other recognised chronic illnesses such as diabetes or cardiovascular disease (Kitihata 2002). Chronic illnesses as defined for this review include both physical and mental illnesses (WHO 2012). The World Health Organisation (WHO) has projected that the proportion of deaths due to chronic illnesses would rise from 59% in 2002 to 69% in 2030 (WHO 2002). More recently, WHO reported that chronic diseases such as heart disease, stroke, cancer, chronic respiratory diseases and diabetes are the leading causes of mortality in the world, representing 60% of all deaths (WHO 2012).

A significant proportion of people with chronic illness do not receive appropriate care (Schoen 2009). Studies in the United States and Netherlands suggest that 30 to 40% of patients do not receive care according to current scientific evidence, while 20% or more of the care provided is not needed, or may be harmful to patients (Grol 2003; Garman 2006). McGlynn 2003, surveying 12 metropolitan areas in the United States, found that only 56% of people with chronic illnesses received recommended medical treatment. An examination of the experiences of chronically-ill patients across eight countries found major differences in access, safety and care efficiency, with these patients at particular risk of experiencing inefficient, poorly-organised care or errors (Schoen 2009).

There are a number of reasons as to why people with chronic illness do not receive the type and level of care that is recommended. Deficits in care management during hospital discharge or when

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seeing multiple doctors are common (Schoen 2009), highlighting the need for system innovations to improve outcomes for patients with complex chronic illnesses. A survey of 'sicker adults' across Australia, Canada, New Zealand, UK and USA, reported that 33 to 49% of respondents were not given advice on health risk behaviours (such as weight, nutrition, exercise, smoking and at risk alcohol use) and that 47 to 67% were not asked for their input into treatment options (Blendon 2003). Another concern relates to inadequate patient involvement in health care, which is particularly evident in mental health. Reports have found that less than 15% of patients with chronic illnesses such as major depression, panic disorder or generalised anxiety disorder, receive evidence-based treatment (Wang 2000; Horsfall 2010). People with chronic illnesses may not have adequate control of their condition (Frijling 2001; Primatesta 2004; McKinstry 2006) and general practitioners can overestimate patients' adherence to guidelines (Steinman 2004).

People with chronic illnesses increasingly are expected to contribute to decision making around their health care and disease management (Montori 2006), but they do not always have access to appropriate evidence-based information. As a result, some patients will turn to resources such as the Internet which may not always offer the most appropriate information, as they may be out-of-date, or may reflect the views of specific interest groups (e.g., pharmaceutical companies or professional associations). In some cases the advice thus obtained can have negative health consequences (Eysenbach 1999; Hardey 2001; Scullard 2010). Recent research into the accuracy and reliability of medical advice over the internet found that news sites only gave correct advice in 55% of cases (based on current United Kingdom gold standard recommendations), whilst no sponsored sites encountered in the study gave the correct advice (Scullard 2010). There is, therefore, a need for accurate and reliable information for people with chronic diseases.

Increasingly, clinicians have become aware of the impact of using patients' expertise to assist with their own disease management (DOH 2001; Epping-Jordan 2001; Wagner 2001; Kennedy 2002; Martinez 2009; Musacchio 2011). However, clinical and research developments in this area have been slow. This may be partly due to the anxieties and skepticism of some healthcare professionals, who fear that more, rather than less time will be needed to manage 'expert' patients (Shaw 2004; Fox 2005). Additional barriers relate to conflicting notions of who is responsible for managing the illness: the patient or their care provider (Anderson 2005; Fox 2005; Gagliardi 2008). It has been reported that not all patients want to be accountable for the overall management of their health (Henwood 2003), believing instead that this is the role of their healthcare professional. In addition, a 2005 study found that patients felt that they did not possess the technical competence to become adept in self-management (Fox 2005).

Description of the intervention

For the purpose of this review a consumer self-care guideline is an educational guideline designed to encourage patient participation in the management of their chronic disease. We will include guidelines provided to patients by a healthcare professional that seek to enhance their understanding of their illness and recommend standards of care and treatment options to be discussed with their healthcare professional. Guidelines are increasingly produced by a wide range of organisations, but we will include only those produced in consultation with health professionals or are accepted as an established national guideline.

Consumer self-care guidelines as defined for this review are aimed at two areas, firstly to promote self-care or self-management by increasing patient participation in the management of their chronic disease, and secondly to enhance patient understanding of their illness. Promotion of self-care seeks to encourage people to take responsibility for their own health and well-being. According to the National Health Service (NHS 2009), self-care is a working partnership between the individual and their care professional by communication, negotiation and decision-making processes to achieve the best possible outcome for the individual. Self-care refers to empowering individuals in a supportive, non-threatening manner, by promoting health and well-being and providing tools and resources to manage their own healthcare needs.

Extensive, well-researched guidelines exist for all chronic illnesses, including chronic obstructive pulmonary disease (GOLD 2010), asthma, (Kroegel 2009), hypertension (AACE 2006), type II diabetes (RACGP 2011), irritable bowel syndrome (NICE 2008) and depression (CBC 2011). Clinical guidelines can use different types of evidence with varying levels of validity and reliability (Higgins 2011; Hillier 2011). Consolidating an often complicated body of evidence can be problematic for guideline developers, and where empirical evidence is not available, guidelines may use consensus-based expert opinion or provide recommendations with a disclaimer that the area requires further research (Gagliardi 2009). Numerous tools have been developed to determine the reliability of such evidence, including the Jadad score (Clark 1999), NHMRC evidence ratings (NHMRC 2009), FORM (Hillier 2011) and GRADE tools (Grading of Recommendations Assessment, Development, and Evaluation) (Guyatt 2011). These assessments are important when considering the reliability of such information for consumer self-care guidelines and this will be examined within the review.

How the intervention might work

Consumer self-care guidelines might work by providing patients with the resources so that they can take a more active role in their health care. Patients with effective self-management skills reportedly make better use of health professionals' time and subsequently have enhanced self-care (Barlow 2000; Bourbeau 2009). Evidence

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suggests that some patients want a more active role in their health care (Anderson 1995; Anderson 1996; Day 2000; Montori 2006) and this results in increased feelings of control, which one author suggests may have significant health benefits (Kennedy 2006). Through everyday decisions, which are influenced by attitudes and knowledge regarding medications, self-management and exercise, people with chronic illnesses will influence the course and severity of their disease (Bourbeau 2009) as well as their everyday quality of life. In the primary care setting there is increasing evidence that patients' expectations of treatment have significant effects on the treatment they actually receive from their healthcare provider (Howitt 1999; Tomlin 1999; McKinstry 2006). Giving consumers guidelines containing the latest evidence-based recommendations for treating their chronic condition may prompt them to talk with their physician about treatment options. Reducing the need for professional input may increase the cost-effectiveness of care and reduce 'inappropriate' demands on healthcare providers (Troop 1993; Kennedy 2006). Moreover, guidelines synthesise a large amount of information. Given the magnitude of new evidence, and the gap that already exists, patient-directed educational resources offer a potential bridge to narrow this gap (Smith 2003).

Why it is important to do this review

In conducting this review we aim to consolidate and critically analyse trials of consumer-directed self-care guidelines for chronic diseases, in order to uncover which strategies work best for appropriate, acceptable and effective patient care. As a result this review will act as a guide for future clinical practice initiatives and health service investment in patient-directed resources. Incorporating new knowledge into clinical practice has been slow, uneven and at times resisted (Garman 2006). Providing evidence-based resources to patients is considered vital to enable them to more actively manage their health (WHO 2005). As treatment of chronic illness is being directed increasingly at the community level, the role of the patient in understanding and managing their own health is growing more important (Coster 2009). There is little evidence consolidation on this intervention, which may prove to be a cost-effective approach to patient self-care.

OBJECTIVES

To assess the effects of consumer guidelines for people with chronic illnesses, on health outcomes.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials, including cluster randomised controlled trials.

Types of participants

People with a chronic disease meeting the World Health Organisation definition, being 'a disease of long duration and generally slow progression' (WHO 2012), in contrast to an acute illness which is expected to resolve completely within a relatively short period of time.

Chronic diseases include asthma, chronic obstructive pulmonary disease, hypertension, irritable bowel syndrome, diabetes mellitus, Ischaemic heart disease, epilepsy, schizophrenia, depression, anxiety, Parkinson's disease, Alzheimer's disease, HIV/AIDS, cancer, arthritis and renal failure (WHO 2012). Obesity (as defined by study authors) will also be considered as a chronic disease (Bray 2004).

We will exclude studies of people without an established chronic illness, such as those who only have a family history of a disease or who have high risk factors.

We will include people of all age groups, as well as informal caregivers and parents of children with a chronic illness, who also receive the intervention.

Types of interventions

The primary purpose of a consumer guideline is to provide a patient with an easy-to-follow resource, which will enable a more practical approach to self-management in collaboration with healthcare providers, and enhance their understanding of the illness. To be included in this review, guidelines assessed in studies must:

- include a recommendation for standards of care that should be met with treatment options (i.e., provide suggested treatments within the guideline for the health problems reported);
- be delivered or initiated by a healthcare professional or healthcare worker, such as a doctor, surgeon, visiting ward specialist, nurse, therapist, pharmacist, dietician or researcher, to the patient; and
- be produced in consultation with a healthcare professional, recognised healthcare organisation, or established recognised guideline with the aim of increasing patient participation in chronic disease management.

The intervention could be delivered in various ways, such as face-to-face, via the internet, email or post.

Comparison: No intervention, usual practice, oral education only, minimal written information e.g., pamphlet or standard information or a guideline of comparable intensity, that is not used for chronic disease management.

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Types of outcome measures

Primary outcomes

1. Consumer reported physical health outcomes (including symptom scores or counts related to the disease such as breathlessness, pain scales, tiredness, frequency of bowel movements etc.)
2. Psychological health outcomes (including validated quality of life measures, anxiety and depression scales)
3. Adverse outcomes such as mortality and adverse health events

Secondary outcomes

4. Consumer behaviour (use of guideline recommendations, such as change in use of vaccinations, scans, blood tests, or medication, or involvement in the decision-making process)
5. Consumer knowledge or mastery (level of knowledge or change in knowledge about the disease, illness, treatment) and attitudes (towards the illness, treatment)
6. Process measures (patient-reported guideline usage, reading of the guideline, talked/showed doctor the guideline)
7. Clinical treatment outcomes (including results of investigations such as pulmonary function testing, BMI, biopsies and haematological and biochemical tests)
8. Acceptability of guidelines to the consumer (including satisfaction with the information provided, satisfaction with how it was offered, effectiveness of support provided)
9. Service-delivery outcomes including medical service utilisation and costs to the health system

Search methods for identification of studies

Electronic searches

We will search the following electronic databases:

- The Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library*, latest issue);
- MEDLINE (OvidSP) (1966 to present);
- EMBASE (OvidSP) (1980 to present);
- PsycINFO (OvidSP) (1966 to present);
- ERIC (1966 to present).

We present the search strategy for MEDLINE (OvidSP) in Appendix 1. The search strategies for other databases will be adapted as appropriate. There will be no language or date restrictions.

Searching other resources

We will review reference lists of all included studies and of related reviews to identify potentially relevant citations. In addition, we will make enquiries regarding other published or unpublished studies known to the authors of included studies.
We will search online clinical trial registers for ongoing and recently completed studies, including Controlled Clinical Trials (www.controlled-trials.com), the National Research Register (www.nrr.nhs.uk), government registries (clinicaltrials.gov), WHO registries (http://apps.who.int/trialsearch/) and Trials Central (www.trialscentral.org).

Data collection and analysis

Selection of studies

We will combine search results using reference management software and remove duplicates.
From the title, abstract, or descriptors, KC and NL will independently review all citations identified through the searches to determine potentially-relevant trials. All potentially-relevant studies that clearly do not meet the inclusion criteria will be excluded and the reasons recorded in a table 'Characteristics of Excluded Studies'. Any disagreements will be resolved either by consensus or discussion with a third party (BS). We will collate multiple reports of the same study.

Data extraction and management

A combination of two independent review authors (KC and either NL or MB) will extract the study characteristics, risk of bias data (see Assessment of risk of bias in included studies) and outcome data for all included studies. We will extract data using a standardised form based on the Cochrane Consumer and Communication Review Group's data extraction template (CCRG 2009), before entering it into The Cochrane Collaboration software program Review Manager. KC will correspond with study authors to request any missing or raw data as required. Any disagreements will be resolved either by consensus or inclusion of a third party BS.
We will extract the following information from included studies:

- Methods: aim of study; study design; participant recruitment methods; inclusion/exclusion criteria; informed consent; ethical approval; funding; statistical methods; and consumer involvement;
- Participants: description; geographical location; setting; n-values; age; gender; ethnicity; language; diagnosis; co-morbidities; stage/duration of illness; current treatment; and socio-economic status;
- Interventions: aim of intervention; descriptions of interventions and controls; theoretical basis/source; duration; intervention delivery; provider details; and fidelity/integrity of guidelines (based on reported use of validated guideline resources, attempts to test validity of completed consumer

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guideline and involvement of field experts in creation of the consumer guideline);

- Outcomes: outcome data as specified under 'Types of outcome measures; method of outcome collection; method of follow-up for non-respondents; timing of outcome assessments; and adverse events.
- Risk of bias: see Assessment of risk of bias in included studies.

Assessment of risk of bias in included studies

We will assess and report on the methodological risk of bias of included studies in accordance with the Cochrane Handbook (Higgins 2011) and the guidelines of the Cochrane Consumers and Communication Review Group (Ryan 2011), which recommends the explicit reporting of the following individual elements for RCTs: random sequence generation; allocation sequence concealment; blinding (participants, personnel); blinding (outcome assessment); completeness of outcome data, selective outcome reporting; other sources of bias.

In all cases, two authors will independently assess the risk of bias of included studies, with any disagreements resolved by discussion and consensus. We will contact study authors for additional information about the included studies, or for clarification of the study methods as required. We will incorporate the results of the risk of bias assessment into the review through standard tables, and systematic narrative description and commentary about each of the elements, leading to an overall assessment the risk of bias of included studies and a judgement about the internal validity of the review's results. Risk of Bias for each domain will be assessed as 'high risk of bias', 'low risk of bias' or 'unclear risk of bias' as per the guidelines from table 8.5.d of the Cochrane Handbook (Higgins 2011).

Measures of treatment effect

If possible, a risk ratio (RR) or odds ratio (OR) will be provided for the primary outcome of each trial for dichotomous data and standardised mean difference (SMD) or mean difference (MD) for continuous data. These effect estimates will be standardised so that ratios greater than one and differences between intervention and control groups greater than zero, indicate benefit for the intervention group. Where appropriate, the differences in change scores for relevant outcomes will be analysed. Where required, the statistician AE will be consulted for further advice. In instances where more than one outcome is being reported for each outcome category, we will select the reported outcome that is most closely related to the main purpose of the guideline.

Where repeated measures over time are reported for a single study outcome, the longest follow-up will be used for meta-analyses, whilst each time period will be extrapolated using narrative syntheses and reported in the tables described under Data synthesis below.

Unit of analysis issues

For cluster controlled trials, we will perform the analysis at the level of individual whilst accounting for clustering in the data. For those studies which did not adjust for clustering the actual sample size will be replaced with the effective sample size (ESS), calculated using a rho = 0.02 as per Campbell 2000 and the Cochrane Handbook, section 16.3.4 (Higgins 2011). Trials may use a variety of statistical methods to investigate or compensate for clustering; we will record whether studies used these and whether the significance of any effect was altered.

In the case of multi-arm trials we will include each pair-wise comparison separately, but with shared intervention groups divided out approximately evenly among the comparators. However, if the intervention groups are deemed similar enough to be pooled, the groups will be combined using appropriate formulas in the Cochrane Handbook (table 7.7.a for continuous data and chapter 16.5.4 for dichotomous data) (Higgins 2011).

Dealing with missing data

We will deal with missing data using an available case analysis basis as described in chapter 16.2.2 of the Cochrane Handbook (Higgins 2011). All treatment effects will be based on an intention-to-treat analysis where possible. In the case of missing summary statistics required for meta-analysis (e.g., standard deviations, means and n-values) we will attempt to contact study authors to obtain this information. Loss of participants that occurred before baseline measurements will be assumed to have no effect on the outcome data of the study. We will assess and discuss any losses after the baseline measurements are taken.

Assessment of heterogeneity

Significant heterogeneity is expected in this review due to the likely diversities in the populations and diseases being examined. Within meta-analyses, significant heterogeneity will be determined by a combination of the I^2 statistic ($\geq$ 60%), the Chi^2 statistic (P value of less than 0.05) and visual inspection of the data. In such instances data analysis using the random-effects model will be considered in place of a fixed-effect model. However this will be performed with caution taking into account the possible influence of smaller studies which could over- or under-estimate the true treatment effect. If there are sufficient studies, we will also create tables to examine heterogeneity by comparing effect sizes according to potential effect modifiers (characteristics of the consumer guidelines, single or co-morbid conditions, types of conditions and quality of the comparisons).

Assessment of reporting biases

Providing that more than ten studies are included, we will assess potential reporting biases using a funnel plot. Asymmetry in the

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plot could be attributed to publication bias, but may well be due to true heterogeneity, poor methodological design or artefact. In case of asymmetry, we may include contour lines corresponding to perceived milestones of statistical significance (P = 0.01, 0.05, 0.1 etc.) to funnel plots, which may help to differentiate asymmetry due to publication bias from that due to other factors (Higgins 2011). If fewer than ten studies are included, we will describe the reporting biases in the 'other bias' section of the risk of bias tables.

Data synthesis

We will conduct meta-analyses if relevant, valid data are available from at least two studies of the same design, with interventions that are conceptually similar and measure the same outcome. An estimated pooled weight average for RRs will be calculated using the Mantel-Haenszel fixed-effect model, with 95% confidence intervals. We will use a fixed-effect model for meta-analyses, with the exception of data presenting significant heterogeneity, where the random-effects model will be used. If meta-analysis is not judged appropriate we will use a narrative synthesis, treating the studies individually with consideration of their confidence intervals or reporting the results restricted to the larger, more rigorous studies as suggested in section 10.4.4.1 of the Cochrane Handbook (Higgins 2011). In the presence of multiple variables presented for one study (such as symptom scores), we will extract data on the primary outcome (as defined by the authors of the study) for meta-analysis if appropriate. However, if the study reports more than one outcome and none of them are denoted as the primary variable, we will rank the effect sizes for the variables and take the median value. A summary table including a narrative synthesis of all studies with effect sizes will be presented for the primary and secondary outcomes. We will analyse these data using Review Manager software.

Subgroup analysis and investigation of heterogeneity

Where meta-analysis is possible, heterogeneity may be explored through the following subgroup analyses:

- Disease type being single or co-morbid disease and classifications (e.g., COPD, asthma, irritable bowel syndrome, hypertension etc.), as the impact of disease, treatment and subsequent outcomes are known to vary between classifications.
- Length of follow-up (i.e., less than 12 months or greater than or equal to 12 months), as some outcomes may be time dependant producing different short- compared to long-term results, such as quality of life.
- Intervention characteristics (i.e., printed or electronic guideline, size of guideline and duration of intervention delivery), as consumers may find printed material more user friendly compared to electronic guidelines, however electronic guidelines may be easier to access; a larger guideline may be more intimidating reducing uptake, however a smaller guideline may not be as comprehensive; brief intervention delivery may not be as effective as a more intensive delivery of longer duration, however the difference may not meet the minimally important difference justifying the increased costs and consumer time burden.

Sensitivity analysis

We will conduct sensitivity analyses by excluding studies with a high risk of bias for sequence generation and/or allocation concealment, and studies with participants who have significant co-morbidities. Pecularities of studies under investigation may also be discovered during the review process that require sensitivity analysis as per section 9.7 of the Cochrane Handbook (Higgins 2011).

Consumer participation

Before conducting the review, the protocol was reviewed by two independent consumers suffering from a chronic illness. Consumers were presented with a list of questions relating to the design and layout of the protocol and asked to comment on these. Upon completion of the review two independent consumers suffering from a chronic illness will be asked to provide feedback and comment on the findings of the review. The protocol and review also received feedback from one or more consumers through the Cochrane Consumers and Communication Review Group's standard editorial process.

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* *Indicates the major publication for the study*

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APPENDICES

Appendix 1. MEDLINE search strategy

1. chronic*.hw.
2. ((chronic* or persistent or long* term or ongoing or degenerative) adj3 (disease* or disab* or ill* or condition* or health condition* or medical condition*)).tw.
3. chronic fatigue syndrome.tw.
4. long term care/
5. long* term care.tw.
6. exp neurodegenerative diseases/
7. (neurodegenerative or Huntington* disease or Parkinson* disease or amyotrophic lateral sclerosis or motor neuron disease).tw.
8. exp multiple sclerosis/
9. multiple sclerosis.tw.
10. exp arthritis/
11. (arthritis or osteoarthritis or rheumati*).tw.
12. exp lung diseases obstructive/
13. (obstructive lung disease* or obstructive pulmonary disease* or asthma or bronchitis).tw.
14. exp emphysema/
15. exp pulmonary emphysema/
16. emphysema.tw.
17. exp diabetes mellitus/
18. (diabetes or diabetic).tw.
19. exp hypertension/
20. (hypertension or high blood pressure).tw.
21. exp cerebrovascular disorders/
22. (cerebrovascular disease* or cerebrovascular disorder* or brain ischaemia or cerebral infarction or carotid artery disease* or stroke).tw.
23. exp dementia/
24. (dementia or alzheimer*).tw.
25. exp epilepsy/
26. epilep*.tw.
27. exp myocardial ischaemia/
28. (myocardial ischaemia or angina pectoris or coronary disease* or coronary artery disease* or myocardial infarction).tw.
29. exp heart failure/
30. (heart failure or heart disease*).tw.
31. renal insufficiency/
32. ((renal or kidney) adj (failure* or insufficienc*)).tw.
33. exp colonic diseases/
34. (colonic disease* or colitis or irritable bowel syndrome).tw.
35. exp obesity/
36. (obesity or obese).tw.
37. exp hiv/
38. (hiv infect* or hiv disease*).tw.
39. exp osteoporosis/
40. osteoporosis.tw.
41. fibromyalgia/
42. fibromyalgia*.tw.
43. exp neoplasms/
44. (cancer* or oncolog* or neoplasm* or carcinom* or tumo?r* or malignan*).tw.
45. or/1-44
46. teaching materials/
47. computer assisted instruction/

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48. ((teaching or education* or instruction* or information* or counsel* or train* or self care or self management) adj2 (material* or pack*)).tw.
49. ((written or print* or online or on-line or electronic or computeri#ed or computer-based or web-based or internet-based) adj2 (information or education or material* or pack* or intervention*)).tw.
50. patient held.tw.
51. pamphlets/
52. ((patient? or carer* or caregiver* or care giver* or parent? or self care or self management or self-education*) adj5 (guide* or manual? or booklet? or brochure? or checklist* or folder* or care plan* or management plan* or clinical information)).tw.
53. ((self care or self management or self-education*) and (print* or written or mail* or web* or internet or online or on line or electronic* or email* e-mail* or electronic mail)).tw.
54. patient education as topic/
55. patient education.tw.
56. exp self care/
57. or/54-56
58. electronic mail/
59. internet/
60. (e-mail* or email* or web* or internet or online or on line or electronic* or print* or written or guide* or manual? or booklet? or brochure? or checklist* or folder* or care plan* or management plan*).tw.
61. or/58-60
62. 57 and 61
63. or/46-53
64. 62 or 63
65. 45 and 64
66. randomized controlled trial.pt.
67. controlled clinical trial.pt.
68. randomized.ab.
69. placebo.ab.
70. clinical trials as topic.sh.
71. randomly.ab.
72. trial.ti.
73. or/66-72
74. exp animals/ not humans.sh.
75. 73 not 74
76. 65 and 75

HISTORY

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CONTRIBUTIONS OF AUTHORS

Kristin V Carson is the conceptual director and investigator for the review; contribution will include draft of the protocol, development of search strategy, screening and selection of studies for inclusion, data extraction, data entry, interpretation of analysis, draft for final manuscript and maintenance of updates.

Nadina Labiszewski - Review of protocol draft, screening and selection of studies for inclusion, data extraction, review of final manuscript draft, maintenance of updates.

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Richard Wood-Baker - Review of protocol draft, review of final manuscript draft, maintenance of updates.

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DECLARATIONS OF INTEREST

Brian J Smith is the primary investigator for one study identified for possible inclusion. He will not be involved in identifying studies for inclusion, conducting data extraction or assessing risk of bias.

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