# **BMJ Open**

# Educating professionals to deliver supported selfmanagement to people with asthma or diabetes: protocol for a systematic review and scoping exercise

Journal:	BMJ Open
Manuscript ID	bmjopen-2016-011937
Article Type:	Protocol
Date Submitted by the Author:	16-Mar-2016
Complete List of Authors:	McCleary, Nicola; University of Edinburgh, Asthma UK Centre for Applied Research Andrews, Amanda; Education for Health Morrow, Susan; University of Edinburgh Wiener-Ogilvie, Sharon; NHS Education for Scotland Fletcher, Monica; Education for Health Steed, Liz; Queen Mary University of London Taylor, Stephanie; Queen Mary University of London Pinnock, Hilary; University of Edinburgh
 <b>Primary Subject Heading</b> :	Medical education and training
Secondary Subject Heading:	Respiratory medicine, Diabetes and endocrinology, Health services research, General practice / Family practice
Keywords:	Asthma < THORACIC MEDICINE, Diabetes Mellitus (Types 1 and 2), Professional education, Self-management, Systematic review, Implementation

SCHOLARONE™ Manuscripts

1 2	Educating professionals to deliver supported self-management to people with asthma or diabetes: protocol for a systematic review and scoping exercise
3 4 5	Nicola McCleary, <sup>1</sup> Amanda Andrews, <sup>2</sup> Susan Morrow, <sup>1</sup> Sharon Wiener-Ogilvie, <sup>3</sup> Monica Fletcher, <sup>2</sup> Liz Steed, <sup>4</sup> Stephanie JC Taylor, <sup>4</sup> and Hilary Pinnock <sup>1</sup> on behalf of the IMP <sup>2</sup> ART team
6 7	<sup>1</sup> Asthma UK Centre for Applied Research, Usher Institute of Population Health Sciences and Informatics, University of Edinburgh, Edinburgh, UK
8	<sup>2</sup> Education for Health, Warwick, UK
9	<sup>3</sup> NHS Education for Scotland, Edinburgh, UK
10	⁴Blizard Institute, Queen Mary University of London, London, UK
11	
12 13 14 15 16 17 18 19 20 21	Correspondence to: Nicola McCleary Asthma UK Centre for Applied Research Usher Institute of Population Health Sciences and Informatics University of Edinburgh Doorway 3, Old Medical School Teviot Place Edinburgh EH8 9AG Email: nicola.mccleary@ed.ac.uk Tel: 0131 650 2682
23	Keywords
24 25	Asthma, Diabetes Mellitus (Types 1 and 2), professional education, self-management, systematic review, implementation
26	
27	Word count
28	Abstract: 292
29	Main text: 2622
30	
31 32	Running head: professional education for supported self-management in asthma and diabetes

#### **ABSTRACT**

# Introduction

Supported self-management for asthma helps people adjust their treatment in response to symptom changes. This improves day-to-day control, and reduces the risk of asthma attacks and the need for emergency healthcare. However, implementation remains poor in routine clinical practice. This systematic review is part of a programme of work developing an intervention to help primary care practice teams embed self-management into routine asthma care. The aim of the review is to synthesise the evidence regarding the effectiveness of educational interventions for professionals delivering supported self-management to people with asthma or diabetes (Type 1 and Type 2). These two conditions have the most robust evidence base for the effectiveness of implementing supported self-management.

# Methods and analysis

Electronic searches will be conducted in CENTRAL, MEDLINE, EMBASE, ISI Web of Science, CINAHL, PsycINFO, AMED, Global Health, WHO Global Health Library, ERIC, BNI, RDRB/CME, and Google Scholar. Eligible studies are randomised controlled trials or controlled clinical trials published between 1990 and 2016 which evaluated professional education interventions facilitating asthma or diabetes supported self-management. Further relevant work will be identified from trial registries, citation searching, and through contact with authors of included studies. This will be supplemented by scoping potentially relevant educational packages described in English language policy literature or health service websites. Screening, data extraction, and risk of bias assessment (using the Cochrane Risk of Bias Tool) will be completed by two independent reviewers, with a third reviewer arbitrating where necessary. We plan a theoretically-informed narrative synthesis of the aggregated data as heterogeneity is likely to preclude meta-analysis.

# **Ethics and dissemination**

- Ethical approval is not required for this systematic review. The results will be described in a



# STRENGTHS AND LIMITATIONS OF THIS STUDY

- Comprehensiveness of the synthesis will be ensured through searching a wide range
  of databases, performing both prospective and retrospective citation tracking,
  checking trial registries, and contacting authors of included studies
- The systematic review will be supplemented with a scoping exercise of health service
  websites and related resources to ensure that initiatives introduced by healthcare
  services that are not in the published literature are incorporated into the synthesis
- The review is limited by the high likelihood of heterogeneity precluding quantitative synthesis
- Findings related to effective educational strategies will inform a whole systems
  intervention aiming to facilitate primary care practice teams to embed supported selfmanagement into routine asthma care

#### INTRODUCTION

 Asthma is common (affecting an estimated 5.4 million people in the UK) and responsible for unscheduled consultations, hospital admissions and approximately 1,000 deaths a year in the UK.[1] Much of this morbidity is preventable with appropriate, timely self-management.[2-3] Regular structured review between the patient and a health care professional contributes to assisting the individual to effectively control their asthma,[4] a concept described as 'supported self-management'.[2-3] Though widely-accepted definitions include supporting patients to "deal with the medical, role and emotional management of their conditions",[5] supported self-management in asthma as recommended by guidelines,[2-3] focuses narrowly on adherence to medication/monitoring and the early recognition/remediation of exacerbations, summarised in (written) personal asthma action plans (PAAPs).[4, 6-9]

The Practical Systematic Review of Self-Management Support for long-term conditions (PRISMS) project provided a comprehensive overview of the evidence base for supported self-management in 14 long-term conditions (LTCs).[10] In the context of asthma, the quantitative meta-review identified 23 systematic reviews synthesising data from 261 unique

RCTs encompassing a broad range of demographic, clinical and healthcare contexts, and concluded that supported self-management reduces exacerbations and improves control and quality of life.[10] The qualitative meta-review identified one review which highlighted that patients want a medically focussed PAAP set within the broader concept of 'living with asthma'.[11] Implementation of supported self-management, however, remains poor in routine clinical practice. An Asthma UK survey estimated that only 24% of people with asthma currently have a PAAP.[12] The National Review of Asthma Deaths identified lack of PAAPs as a key preventable factor in the deaths that they investigated.[13] Identified barriers to implementing asthma self-management support are practical (e.g., time, no available paper-based PAAPs [14]); conceptual (e.g., mismatch between professionals' focus on clinical action plans and the advice patients want about 'living with asthma' [11]); and organisational (e.g. professional communication between nurses who provide self-management education and general practitioners (GPs) who treat exacerbations [15]). The systematic review of implementation studies conducted as part of PRISMS concluded that integration into routine practice required a whole systems approach in which motivated, skilled professionals support activated, informed patients within an organisation that values, promotes and monitors the delivery of supported self-management.[16] We are undertaking preliminary work to develop, refine and evaluate the clinical and costeffectiveness of a practice-based intervention to implement self-management support for asthma in routine clinical practice in a UK-wide cluster RCT. An educational package for professionals who support people with asthma to self-manage will form a key component of the whole systems approach. Professional education is a pre-reguisite for effective implementation of supported self-management and will not only need to address the skills

trained general practice nurses in the UK) but also other members of the primary healthcare

required by the professionals delivering self-management education (typically asthma-

team providing services for people with asthma (including GPs, reception staff, prescribing clerks, and community pharmacists).[10]

The aim of this systematic review is therefore to inform the development of the educational package by synthesising the evidence regarding the effectiveness of educational interventions for professionals involved in delivering supported self-management. The review will focus on diabetes as well as asthma in order to go beyond existing interventions in asthma and learn from professional education approaches in another condition where self-management support is well evidenced and fundamental to care. These two conditions have the most robust evidence base for the effectiveness of implementing supported self-management,[10]

# **METHODS AND ANALYSIS**

We will follow systematic review procedures described in the Cochrane Handbook for Systematic Reviews of Interventions.[17] The Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P) checklist has been used to guide the reporting of this protocol.[18] If amendments to the protocol are made, the description of each amendment will be reported along with the amendment number and date. The review commenced on 2<sup>nd</sup> November 2015 and will be completed by 30<sup>th</sup> September 2016.

# Eligibility criteria

# 134 Participants

 The target population is professionals delivering care to people with asthma or Type 1 or Type 2 Diabetes Mellitus. This includes doctors, nurses, or health educators, but primary care practice teams (including clinicians and administrative staff) are of particular interest. In this context, a primary care practice team is a team of professionals working within a practice to deliver patient care. Others who may deliver supported self-management in this context (such as pharmacists or lay/peer educators) will be included if their role is integrated within a practice team.

#### Interventions

Interventions of interest are educational packages designed to train professionals and/or practice teams to deliver education or supported self-management to people with asthma or diabetes. In this context, self-management support is defined as a service intervention that aims to empower patients to be active decision makers who deal with the emotional, social and medical management of their illness and improve their independence and quality of life. [5] These can comprise 14 components (information about condition/management; information about resources; plan/medication provision; regular review; monitoring and feedback; adherence support; equipment provision; access to advice/support; training/rehearsal for: communication with health-care professionals, everyday activities, practical self-management activities, psychological strategies; social support; and lifestyle advice and support).[19]

### Comparators

In most trials of educational interventions, the comparator will be 'no education', though some may compare components of an educational package (for example, different modes of delivery, such as online vs. face-to-face). The nature of the control service will be noted and accommodated within the analysis.

#### Outcomes

As this is a review of implementation-level interventions (i.e. interventions aimed at changing health outcomes through changes in clinical practice), the primary outcomes of interest are categorised into two levels: process-level outcomes, and health outcomes. Process-level outcomes reflect professional behaviour change. The primary process-level outcomes are the proportion of people with asthma receiving PAAPs, and the proportion of people with diabetes receiving structured education.

The ATS/ERS Task Force report on asthma outcome assessment recommended that health outcomes in trials should reflect measures of both current control and future risk.[20] To

maintain consistency, we have applied this recommendation to the selection of primary
health outcomes for both asthma and diabetes in this review. The primary outcomes
representing current control are markers of asthma control (asthma control questionnaire or
similar validated questionnaire), and HbA1c level for diabetes. The primary outcomes
representing future risk are the proportion of people with an unscheduled consultation for
acute asthma deterioration (e.g. out-of-hours/ GP consultation/ A&E/ admission), and acute
events related to diabetic control and necessitating urgent action (e.g. hypoglycemia/
hyperglycemia/ diabetic ketoacidosis).
Secondary outcomes comprise behavioural/cognitive measures related to both professionals
(e.g. improvement in communication skills, confidence, competence) and patients (e.g. self-
efficacy, empowerment, and activation) and other measures of control (e.g. symptom free

181 Study design

 Randomised controlled trials and controlled clinical trials will be included, since educational interventions many not always be evaluated in randomised controlled trials.

days) or future risk (e.g. exacerbations/ steroid courses). When extracting secondary

outcome data, outcomes assessed using validated tools will be prioritised.

- 184 Setting
- Any healthcare setting is of interest, though trials implemented within primary care teams will be of particular interest.
- 187 Years considered
- Studies published from 1990 onwards will be included, as evolving professional educational approaches mean that earlier literature is unlikely to be relevant.
- 190 Language
- There will be no language restrictions for included studies: literature will be translated where possible, and any literature that we are unable to translate will be reported.

#### Information sources

Electronic searches will be conducted in CENTRAL, MEDLINE, EMBASE, ISI Web of Science, CINAHL, PsycINFO, AMED, Global Health, WHO Global Health Library, ERIC, BNI, RDRB/CME, and Google Scholar for studies published from 1990 until 2016. For all included studies, reference lists will be scrutinised and prospective citation tracking will be performed to identify additional relevant studies. We are not aware of any specific journals specialising in this literature which may require hand-searching: however, if such journals become apparent after gathering relevant studies, these will be hand-searched. To identify relevant unpublished and in-progress studies, key internet-based relevant databases will be searched (UK Clinical Research Network Study Portfolio; the meta Register of Controlled Trials, www.clinicaltrials.gov; and www.controlled-trials.com). Relevant qualitative studies which inform educational interventions (e.g., published alongside trials)[21] will be retrieved. Authors of included studies will be contacted to i) source further published or unpublished results and/or training manuals related to their study if available; ii) source other relevant published, unpublished or ongoing studies including any related qualitative studies. We will supplement the published literature review by undertaking a scoping exercise of existing potentially relevant packages in asthma and diabetes through: i) searching English language policy literature and health service websites for information about improvement initiatives involving up-skilling practices/clinical teams to improve self-management; and ii) contacting the initiative leads for information about the packages.

#### Search strategy

A sensitive search strategy has been developed following advice from a senior librarian (Marshall Dozier, University of Edinburgh) using the Ovid interface for MEDLINE (Supplementary File). This will be adapted for searches in other databases.

# Data management

Literature search results will be exported to EndNote Library, which will be used for deduplication, study screening, and overall management of the retrieved records. Microsoft Word will be used to develop a data extraction form, which will be piloted and refined before use. Data will be extracted and stored electronically. Multiple reports from the same study will be treated as a single study, but we will draw on and make reference to all relevant publications.

# **Selection process**

One reviewer (NM) will undertake an initial filter of duplicates and clearly irrelevant titles. Two reviewers (NM and AA) and the joint project leads (HP and ST) will independently screen a sample of 100 titles and abstracts from the searches for inclusion according to the review criteria. Any disagreements will be resolved by discussion and consultation with the project team, if required. This process will be repeated on further samples of 100 titles and abstracts until the level of agreement between all reviewers is deemed satisfactory. The two reviewers will then independently screen all titles and abstracts, selecting potentially eligible papers for full text screening. The full texts of all potentially eligible studies will be retrieved and independently screened by the two reviewers. Disagreements at both stages will be resolved by discussion, or arbitration by a third reviewer (HP or ST) if necessary. If after the full text assessment it is still unclear whether a study fulfils the inclusion criteria, the study authors will be contacted by email for clarification: if this fails, the respective study will be listed as a 'potentially relevant study'. The searching and screening processes will be summarised using a PRISMA flow diagram.[22]

# **Data collection process**

The two reviewers (NM and AA) will extract the main findings from each study onto the data extraction form. The form will be piloted on a sub-sample of included studies to ensure it is easily and consistently interpreted and captures all relevant information. Data extraction

disagreements will be resolved by discussion, or arbitration by a third reviewer (HP or ST) if necessary.

#### **Data items**

Data will be extracted relating to general study characteristics, participant characteristics, details of the intervention and control conditions, the relevant outcomes assessed and corresponding results, and information for assessment of the risk of bias.

#### Risk of bias in individual studies

The two reviewers (NM and AA) will conduct independent assessments of methodological quality and risk of bias using the Cochrane Risk of Bias Tool.[23] Disagreements will be resolved by discussion or, if necessary, arbitration by a third reviewer (HP or ST). The resulting risk of bias in included studies will be used to evaluate the robustness of the findings.

#### **Data synthesis**

Descriptive tables will be used to summarise the characteristics of included studies.

Frameworks such as TIDieR (a template for reporting interventions)[24] and/or the
Theoretical Domains Framework (a validated framework that identifies domains of
theoretical approaches to behaviour change interventions which has been applied
retrospectively to published interventions)[25-27] will be used to describe the interventions.

On a practical level, in order to inform the development of the educational component for our
proposed implementation intervention, we will also take into account any frameworks used
by Education for Health in the development of their courses.

A detailed descriptive summary of studies will be compiled, including data under the
headings of: setting (primary/secondary care); at whom the intervention is directed

(individual professional, groups, practice teams); mode of delivery (group, individual, face-to-

face, on-line); components (lectures, workshops, assignments, practical skills, mentorship);

duration and intensity of education/mentoring, generic/disease focused, outcomes assessed, information about uptake and any information about fidelity. We may undertake some short telephone interviews with authors in order to enhance our understanding of the interventions. Based on preliminary scoping work, it is anticipated that there will be substantial heterogeneity so that meta-analysis will not be appropriate. A narrative synthesis of the aggregate data will therefore be undertaken. This will be achieved by developing a matrix of what has been shown to be effective/ineffective and the elements of the educational package (including content, mode of delivery, duration, intensity). Depending on the available data, graphical techniques (e.g. Harvest plots [28]) may be used to illustrate key outcomes and their relationship to these elements. Qualitative data will be used to enhance our understanding of participants' perceptions of the impact of participating in the educational intervention on their professional practice. Data from qualitative studies will be synthesised thematically.[29] An overarching narrative synthesis of quantitative and qualitative findings will be undertaken.[30] Depending on the extent of the literature available in the different disease areas, sub-group analyses may be undertaken according to the targeted professionals (doctor, nurse, practice team) and/or setting (primary/secondary care). The findings of the scoping exercise of existing potentially relevant packages in asthma and diabetes will be used to supplement those of the systematic review. The multidisciplinary research team, the wider project team and the steering group will meet regularly to discuss the emerging findings and aid interpretation. The PRISMA checklist will be used to guide reporting of the review [22]

# **REGISTRATION**

 The protocol for this review has been registered with the International Prospective Register of Systematic Reviews (PROSPERO; 2016:CRD42016032922).

#### **ETHICS AND DISSEMINATION**

Ethical approval is not required for this study, given that it is a systematic review utilising data already in the public domain. This review will inform the educational component of a whole systems intervention that will help primary care practice teams embed supported self-management into routine asthma care. A paper describing the review will be submitted for peer-reviewed publication. The infrastructure of the Asthma UK Centre for Applied Research (AUKCAR) will be used to support innovative approaches to dissemination (e.g. via social media and Science Festivals).

# **CONCLUSION**

Whilst patient education, professional training and organisational support are all essential components of successful self-management support, they are rarely effective in isolation.[10] Effective implementation is multi-faceted and multidisciplinary: it involves engaging patients and training and motivating professionals within the context of an organisation which actively supports self-management.[10, 16] This review will achieve clarity on educational strategies likely to be effective in enabling professionals to implement supported self-management in their clinical practice, and will inform one component of a whole systems intervention aiming to facilitate primary care practice teams to embed supported self-management into routine asthma care.

# **REFERENCES**

- Asthma UK. Asthma facts and statistics. Available from http://www.asthma.org.uk/asthma-facts-and-statistics (accessed Feb 2016)
- British Thoracic Society/Scottish Intercollegiate Guideline Network. British Guideline
  on the Management of Asthma: 2014 update. *Thorax* 2014;69(Suppl1):1-192.
   Available from <a href="http://www.sign.ac.uk">http://www.sign.ac.uk</a> (accessed Feb 2016)
- 3. Global Initiative for Asthma. *Global Strategy for Asthma Management and Prevention*, 2014. Available from <a href="http://www.ginasthma.org">http://www.ginasthma.org</a> (accessed Feb 2016)

320	4.	Gibson PG, Powell H, Wilson A, et al. Self-management education and regular
321		practitioner review for adults with asthma. Cochrane Database of Systematic
322		Reviews 2002, Issue 3. Art.No:CD001117
323	5.	Adams K, Greiner AC, Corrigan JM. Eds. The 1st Annual Crossing the Quality
324		Chasm Summit – A Focus on Communities. Washington, DC: The National
325		Academic Press 2004:57
326	6.	Tapp S, Lasserson TJ, Rowe BH. Education interventions for adults who attend the
327		emergency room for acute asthma. Cochrane Database of Systematic Reviews
328		2007, Issue 3. Art.No:CD003000
329	7.	Gibson PG, Powell H. Written action plans for asthma: an evidence-based review of
330		the key components. <i>Thorax</i> 2004;59:94–99
331	8.	Toelle B, Ram FSF. Written individualised management plans for asthma in children
332		and adults. Cochrane Database of Systematic Reviews 2004, Issue 1.
333		Art.No:CD002171
334	9.	Lefevre F, Piper M, Weiss K, et al. Do written action plans improve patient outcomes
335		in asthma? An evidence-based analysis. J Fam Prac 2002;51:842–848
336	10	. Taylor SJC, Pinnock H, Epiphaniou E, et al. A rapid synthesis of the evidence on
337		interventions supporting self-management for people with long-term conditions.
338		(PRISMS Practical Systematic Review of Self-Management Support for long-term
339		conditions) Health Serv Deliv Res 2014;2:54
340	11	. Ring N, Jepson R, Hoskins G, et al. Understanding what helps or hinders asthma
341		action plan use: a systematic review and synthesis of the qualitative literature. Pat Ed
342		Counsel 2011;85:e131-e143
343	12	. Asthma UK. Time to take action on asthma. Available from
344		https://www.asthma.org.uk/globalassets/campaigns/compare-your-care-2014.pdf
345		(accessed Feb 2016)
346	13	. Royal College of Physicians. Why asthma still kills: the National Review of Asthma
347		Deaths (NRAD) Confidential Enquiry report. London: RCP 2014
		14

348	14. Wiener-Ogilvie S, Pinnock H, Huby G, et al. Do practices comply with key
349	recommendations of the British Asthma Guideline, and if not, why not? Prim Care
350	Resp J 2007;16:369-377
351	15. Weiner-Ogilvie S, Huby G, Pinnock H, et al. Practice organisational characteristics
352	can impact on compliance with the BTS/SIGN asthma guideline: qualitative
353	comparative case study in primary care. BMC Fam Pract 2008;9:32
354	16. Pinnock H, Epiphaniou E, Pearce G, et al. Implementing supported self-management
355	for asthma: a systematic review of implementation studies. BMC Med 2015;13:127
356	17. Higgins JPT, Green S. Eds. Cochrane Handbook for Systematic Reviews of
357	Interventions. Version 5.1.0 [updated March 2011]. The Cochrane Collaboration,
358	2011. Available from <a href="http://handbook.cochrane.org/">http://handbook.cochrane.org/</a> (accessed Feb 2016)
359	18. Shamseer L, Moher D, Clarke M, et al. Preferred reporting items for systematic
360	review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation.
361	BMJ 2015;349:g7647
362	19. Pearce G, Parke H, Pinnock H, et al. The PRISMS taxonomy of self-management
363	support: derivation of a novel taxonomy and initial testing of utility. J Health Serv Res
364	Policy 2015:1355819615602725[Epub ahead of print]
365	20. Reddel HK, Taylor DR, Bateman ED, et al. An Official American Thoracic
366	Society/European Respiratory Society statement: asthma control and exacerbations
367	standardizing endpoints for clinical asthma trials and clinical practice. Am J Respir
368	Crit Care Med 2009;180:59–99
369	21. Barnett-Page E, Thomas J. <i>Methods for Research Synthesis Node</i> . Evidence for
370	Policy and Practice Information and Co-ordinating (EPPI-)Centre, Social Science
371	Research Unit, Institute of Education. Available from
372	http://eppi.ioe.ac.uk/cms/Default.aspx?tabid=188 (Accessed Feb 2016)
373	22. Moher D, Liberate A, Tetzlaff J, et al. Preferred Reporting Items for Systematic
374	Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med
375	2009;6(7):e1000097
	15

376	23. Higgins JPT, Altman DG, Sterne JAC, on behalf of the Cochrane Statistical Methods
377	Group and the Cochrane Bias Methods Group. Chapter 8: Assessing risk of bias in
378	included studies. Available from
379	http://handbook.cochrane.org/chapter 8/8 assessing risk of bias in included studi
380	es.htm (Accessed Feb 2016)
381	24. Hoffmann T, Glasziou P, Boutron I, et al. Better reporting of interventions: template
382	for intervention description and replication (TIDieR) checklist and guide. BMJ
383	2014;348:g1687
384	25. Michie S, Johnston M, Abraham C, et al. Making psychological theory useful for
385	implementing evidence based practice: a consensus approach. Qual Saf Health Care
386	2005;14:26-33
387	26. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for
388	use in behaviour change and implementation research. Implement Sci 2012;7:37
389	27. Little EA, Presseau J, Eccles MP. Understanding effects in reviews of implementation
390	interventions using the Theoretical Domains Framework. Implement Sci 2015;10:90
391	28. Ogilvie D, Fayter D, Petticrew M, et al. The harvest plot: a method for synthesising
392	evidence about the differential effects of interventions. BMC Med Res Methodol
393	2008;8:8
394	29. Thomas J, Harden A. Methods for the thematic synthesis of qualitative research in
395	systematic reviews. BMC Med Res Methodol 2008;8:45
396	30. Ring N, Jepson R, Pinnock H, et al. Developing novel evidence-based interventions
397	to promote asthma action plan use: a cross-study synthesis of evidence from
398	randomised controlled trials and qualitative studies. Trials 2012;13:216
399	ACKNOWLEDGEMENTS
400	The authors thank Marshall Dozier, Senior Liaison Librarian and Liaison Director for the
401	College of Medicine and Veterinary Medicine at the University of Edinburgh, who assisted in
402	developing the search strategy.

#### **AUTHORS' CONTRIBUTIONS**

HP and ST conceived the idea for this work and are the guarantors. The protocol was drafted by NM and was then revised after several rounds of critical comments and additional feedback from AA, SM, SW-O, MF, LS, ST and HP. All authors will be involved in the systematic review process.

The IMP<sup>2</sup>ART team also includes Aziz Sheikh, Brian McKinstry, and Luke Daines (University of Edinburgh); Chris Griffiths and Sandra Eldridge (Queen Mary University of London); Anne-Louise Caress (University of Manchester); Elisabeth Ehrlich (Asthma UK Centre for Applied Research); Bethan Haskins (Canterbury and Coastal Clinical Commissioning Group); Rob Horne (University College London); Steven Julious (University of Sheffield);

# **COMPETING INTERESTS**

Monica Fletcher is the Chief Executive for Education for Health, an organisation that provides training for healthcare professionals. The authors declare no further competing interests related to this work.

Lorna McKee (University of Aberdeen); and Ceri Phillips (University of Swansea).

#### **FUNDING**

This report is independent research funded by the National Institute for Health Research (Programme Development Grants, Implementing supported asthma self-management in routine clinical care: designing, refining, piloting and evaluating a whole systems implementation within an MRC Phase IV programme of research, RP-DG-1213-10008). The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health. This work is sponsored by the University of Edinburgh. The funder and sponsor have not had any role in developing the protocol.

#### SUPPLEMENTARY FILE

1 2

3 4

5 6

7

8

9

10

11

12 13

14

15

16

17

18

19

20

21

22 23

24

25

26

27

28

29

30

31

32

33

34 35

36

37

38

39

40

41

42

43

44

45 46

47

48

49

50

51

52

53

54

55

56

57 58

59 60

# **MEDLINE Search Strategy**

- 1. Primary Health Care/ or Family Practice/ or General Practice/
- 2. (primary care or primary medical care or primary health care or primary healthcare or general practice or family practice).mp.
- 3. Health Personnel/ or Medical Staff/
- 4. ((healthcare or health care) adj3 (provider? or practitioner? or professional?)).mp.
- 5. Physicians/ or Physicians, Primary Care/ or Physicians, Family/ or General Practitioners/
- 6. (general practitioner? or medical practitioner? or physician? or clinician? or doctor? or GP?).mp.
- 7. Nurses/ or Nursing Staff/ or Nurse Practitioners/ or Family Nurse Practitioners/
- 8. (nurse? or practice nurse? or community nurse? or nurse practitioner?).mp.
- 9. Medical Secretaries/ or Medical Receptionists/
- 10. (secretar\$ or reception\$ or administrat\$).mp.
- 11. Pharmacists/
- 12. pharmacist?.mp.
- 13. Health Educators/
- 14. health educator?.mp.
- 15. Patient Care Team/
- 16. ((primary care or primary care practice or health care or healthcare or medical care or general practice or family practice) adj3 team?).mp.
- 17. or/1-16
- 18. Education/ or Health Education/
- 19. (educat\$ or train\$).mp.
- 20. (skill? adj3 develop\$).mp.
- 21. Education, Professional/ or Education, Continuing/
- 22. (professional development or CPD).mp.
- 23. ((interprofessional or inter professional or inter-professional) adj3 (educat\$ or train\$ or develop\$ or skill?)).mp.
- 24. ((team? or group?) adj3 (educat\$ or train\$ or develop\$ or skill?)).mp.
- 25. Education, Medical/ or Education, Medical, Continuing/
- 26. (continuing medical education or CME).mp.
- 27. Education, Nursing/ or Education, Nursing, Continuing/ or Nursing Education Research/ or Nursing Evaluation Research/
- 28. Education, Pharmacy/ or Education, Pharmacy, Continuing/
- 29. Quality Improvement/
- 30. (quality adj3 improv\$).mp.
- 31. or/18-30
- 32. Disease Management/
- 33. disease management.mp.
- 34. Self Care/ or Self Administration/ or Self Medication/
- 35. (self-manag\$ or selfmanag\$ or self-car\$ or selfcar\$ or self-help or selfhelp or self-administrat\$ or selfadministrat\$ or self-monitor\$ or selfmonitor\$ or self-medicat\$ or selfmedicat\$).mp.
- 36. (self adj3 (manag\$ or car\$ or help or administrat\$ or monitor\$ or medicat\$)).mp.
- 37. Quality of Health Care/
- 38. (quality adj3 (care or healthcare or health care)).mp.
- 39. Professional-Patient Relations/ or Physician-Patient Relations/ or Nurse-Patient Relations/

4

5

6

7

8

9

10

11

12

13 14

15

16

17

18

19

20

21

22

23

24

25 26

27

28

29

30

31

32

33

34

35

36 37

38

39

40

41

42

43

44

45

46 47

48

49

50

51

52

53

54

55

56

57

- 40. (patient? adj3 (relation\$ or communicat\$)).mp.
- 41. ((action or treat\$ or car\$ or written or manag\$ or medicat\$) adj3 plan\$).mp.
- 42. ((self-manag\$ or self manag\$ or selfmanag\$ or self-car\$ or self car\$ or selfcar\$ or self-help or self help or selfhelp or self-administrat\$ or self administrat\$ or selfadministrat\$ or self-monitor\$ or selfmonitor\$ or self-medicat\$ or self medicat\$ or selfmedicat\$ or self-treat\$ or self treat\$ or selftreat\$) adj3 plan\$).mp.
- 43. (exacerbat\$ or attack?).mp.
- 44. asthma control test.mp.
- 45. Hospitalization/
- 46. hospitali?ation?.mp.
- 47. After-Hours Care/
- 48. (out of hours or out-of-hours or OOH).mp.
- 49. Office Visits/
- 50. ((office or hospital or emergency department or ED or A&E or A & E or "accident and emergency") adj3 (visit\$ or refer\$ or admission\$)).mp.
- 51. ((care or service?) adj3 (utili?ation or use?)).mp.
- 52. Patient Education/
- 53. Blood Glucose Self Monitoring/
- 54. Hemoglobin A, Glycosated/
- 55. HbA1c.mp.
- 56. Hypoglycemia/ or Hyperglycemia/
- 57. Diabetic Ketoacidosis/ or Hyperglycemic Hyperosmolar Nonketotic Coma/
- 58. (hyperosmolar hyperglyc?emic nonketotic syndrome or DKA or HNNS or HONK).mp.
- 59. glyc?emic control.mp.
- 60. or/32-59
- 61. Asthma/
- 62. (asthma or wheez\$).mp.
- 63. (antiasthma\$ or anti-asthma\$).mp.
- 64. Respiratory Hypersensitivity/
- 65. ((bronchial\$ or respiratory or airway\$ or lung\$) adj3 (hypersensitive\$ or hyperreactiv\$ or allerg\$ or insufficiency)).mp.
- 66. Bronchial Spasm/
- 67. Bronchoconstriction/
- 68. (bronch\$ adj3 (constrict\$ or spas\$)).mp.
- 69. (bronchoconstrict\$ or bronchospas\$).mp.
- 70. bronchial hyperreactivity.mp.
- 71. respiratory sounds.mp.
- 72. Diabetes Mellitus/
- 73. diabet\$.mp.
- 74. Diabetes Mellitus, Type 1/
- 75. ((diabet\$ or dm) adj5 (typ\$ adj3 (one or "1" or I))).mp.
- 76. Diabetes Mellitus, Type 2/
- 77. ((diabet\$ or dm) adj5 (typ\$ adj3 (two or "2" or II))).mp.
- 78. Insulin Resistance/
- 79. ((insulin or noninsulin or non-insulin) adj3 (resistan\$ or depend\$)).mp.
- 80. (DM or DM1 or DM2 or T1D or T1DM or T2D or T2DM or NIDDM or IDDM or MODY).mp.
- 81. glucose \$tolerance.mp.
- 82. or/61-81
- 83. Pragmatic Clinical Trial/ or Clinical Trial/ or Randomized Controlled Trial/ or Controlled Clinical Trial/

- 84. randomi?ed controlled trial.pt.
- 85. controlled clinical trial.pt.
- 86. (randomi?ed or randomly).ti,ab.
- 87. trial.ti,ab.

- 88. group?.ti,ab.
- 89. or/83-88
- 90. 17 and 31 and 60 and 82 and 89
- 91. (letter or review or comment or editorial).pt.
- 92. 90 not 91
- 93. (Animals/ or Nonhuman/) not Humans/
- 94. 92 not 93

Note: a free-text term related to professional behaviour (prof\$ adj3 behav\$).mp.) was considered for inclusion in section two of the above search, which is focussed on ons. hu. additional to thu. educational interventions. However, it was not included because when added, it did not retrieve any records additional to those already retrieved.

# PRISMA-P 2015 Checklist

This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 3 in Moher D et al: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 **4**:1

Castianhania	#	Oh a a biling to its array	Information reported		Line
Section/topic		Checklist item		No	number(s)
ADMINISTRATIVE INFO	RMAT	ION			
Title					
Identification	1a	Identify the report as a protocol of a systematic review			2
Update	1b	If the protocol is for an update of a previous systematic review, identify as such			N/A
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract			62
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author			a-20 e-mail address provided for corresponding author only, per journal instructions
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review			404-407
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments			130-131
Support					
Sources	5a	Indicate sources of financial or other support for the review			419-426
Sponsor	5b	Provide name for the review funder and/or sponsor			419-426
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol			419-426



Castianltonia	<u> </u>	Charlist item	Information reported		Line
Section/topic	#	Checklist item	Yes	No	number(s)
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known			76-117
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)			118-125
METHODS					
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review			134-192
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage			194-213
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated			215-217 & supplementary file
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review			219-224
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)			226-239
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators			241-245 205-213
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications			247-249
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale			160-180
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis			251-255
DATA					



Castian/tania	#	# Observation # 1	Information reported		Line
Section/topic	#	Checklist item	Yes	No	number(s)
	15a	Describe criteria under which study data will be quantitatively synthesized			N/A 272-274
Synthesis	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I <sup>2</sup> , Kendall's tau)			N/A
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)			283-285
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned			273-290
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)			N/A
Confidence in cumulative evidence 17 Describe how the strength of the body of evidence will be assessed (e.g., GRADE)				N/A	



# **BMJ Open**

# Educating professionals to support self-management in people with asthma or diabetes: protocol for a systematic review and scoping exercise

Journal:	BMJ Open
Manuscript ID	bmjopen-2016-011937.R1
Article Type:	Protocol
Date Submitted by the Author:	29-Jun-2016
Complete List of Authors:	McCleary, Nicola; University of Edinburgh, Asthma UK Centre for Applied Research Andrews, Amanda; Education for Health Morrow, Susan; University of Edinburgh Wiener-Ogilvie, Sharon; NHS Education for Scotland Fletcher, Monica; Education for Health Steed, Liz; Queen Mary University of London Taylor, Stephanie; Queen Mary University of London Pinnock, Hilary; University of Edinburgh
 <b>Primary Subject Heading</b> :	Medical education and training
Secondary Subject Heading:	Respiratory medicine, Diabetes and endocrinology, Health services research, General practice / Family practice
Keywords:	Asthma < THORACIC MEDICINE, Diabetes Mellitus (Types 1 and 2), Professional education, Self-management, Systematic review, Implementation

SCHOLARONE™ Manuscripts

Educating professionals to support self-management in people with asthma or diabetes: protocol for a systematic review and scoping exercise
Nicola McCleary, <sup>1</sup> Amanda Andrews, <sup>2</sup> Susan Morrow, <sup>1</sup> Sharon Wiener-Ogilvie, <sup>3</sup> Monica Fletcher, <sup>2</sup> Liz Steed, <sup>4</sup> Stephanie JC Taylor, <sup>4</sup> and Hilary Pinnock <sup>1</sup> on behalf of the IMP <sup>2</sup> ART team
<sup>1</sup> Asthma UK Centre for Applied Research, Usher Institute of Population Health Sciences and Informatics, University of Edinburgh, Edinburgh, UK
<sup>2</sup> Education for Health, Warwick, UK
<sup>3</sup> NHS Education for Scotland, Edinburgh, UK
<sup>⁴</sup> Blizard Institute, Queen Mary University of London, London, UK
Correspondence to: Nicola McCleary Asthma UK Centre for Applied Research Usher Institute of Population Health Sciences and Informatics University of Edinburgh Doorway 3, Old Medical School Teviot Place Edinburgh EH8 9AG Email: nicola.mccleary@ed.ac.uk Tel: 0131 650 2682
Keywords
Asthma, Diabetes Mellitus (Types 1 and 2), professional education, self-management, systematic review, implementation
Word count
Abstract: 292
Main text: 2900
Running head: educating professionals to support self-management in asthma and diabetes

#### **ABSTRACT**

# Introduction

Supported self-management for asthma helps people adjust their treatment in response to symptom changes. This improves day-to-day control, and reduces the risk of asthma attacks and the need for emergency healthcare. However, implementation remains poor in routine clinical practice. This systematic review is part of a programme of work developing an intervention to help primary care practice teams embed self-management support into routine asthma care. The aim of the review is to synthesise the evidence regarding the effectiveness of educational interventions for professionals supporting self-management in people with asthma or diabetes (Type 1 and Type 2). These two conditions have the most robust evidence base for the effectiveness of implementing supported self-management.

# Methods and analysis

Electronic searches will be conducted in CENTRAL, MEDLINE, EMBASE, ISI Web of Science, CINAHL, PsycINFO, AMED, Global Health, WHO Global Health Library, ERIC, BNI, RDRB/CME, and Google Scholar. Eligible studies are randomised controlled trials or controlled clinical trials published between 1990 and 2016 which evaluated professional education interventions facilitating asthma or diabetes supported self-management. Further relevant work will be identified from trial registries, citation searching, and through contact with authors of included studies. This will be supplemented by scoping potentially relevant educational packages described in English language policy literature or health service websites. Screening, data extraction, and risk of bias assessment (using the Cochrane Risk of Bias Tool) will be completed by two independent reviewers, with a third reviewer arbitrating where necessary. We plan a theoretically-informed narrative synthesis of the aggregated data as heterogeneity is likely to preclude meta-analysis.

# **Ethics and dissemination**

- Ethical approval is not required for this systematic review. The results will be described in a



# STRENGTHS AND LIMITATIONS OF THIS STUDY

- Comprehensiveness of the synthesis will be ensured through searching a wide range
  of databases, performing both prospective and retrospective citation tracking,
  checking trial registries, and contacting authors of included studies
- The systematic review will be supplemented with a scoping exercise of health service
  websites and related resources to ensure that initiatives introduced by healthcare
  services that are not in the published literature are incorporated into the synthesis
- The review is limited by the high likelihood of heterogeneity precluding quantitative synthesis
- Findings related to effective educational strategies will inform a whole systems
  intervention aiming to facilitate primary care practice teams to embed supported selfmanagement into routine asthma care

#### INTRODUCTION

 Asthma is common (affecting an estimated 5.4 million people in the UK) and responsible for unscheduled consultations, hospital admissions and approximately 1,000 deaths a year in the UK.[1] Much of this morbidity is preventable with appropriate, timely self-management.[2-3] Regular structured review between the patient and a health care professional contributes to assisting the individual to effectively control their asthma,[4] a concept described as 'supported self-management'.[2-3] Though widely-accepted definitions include supporting patients to "deal with the medical, role and emotional management of their conditions",[5] supported self-management in asthma as recommended by guidelines,[2-3] focuses narrowly on adherence to medication/monitoring and the early recognition/remediation of exacerbations, summarised in (written) personal asthma action plans (PAAPs).[4, 6-9]

The Practical Systematic Review of Self-Management Support for long-term conditions (PRISMS) project provided a comprehensive overview of the evidence base for supported self-management in 14 long-term conditions (LTCs).[10] In the context of asthma, the quantitative meta-review identified 23 systematic reviews synthesising data from 261 unique

 RCTs encompassing a broad range of demographic, clinical and healthcare contexts, and concluded that supported self-management reduces exacerbations and improves control and quality of life.[10] The qualitative meta-review identified one review which highlighted that patients want a medically focussed PAAP set within the broader concept of 'living with asthma'.[11] Implementation of supported self-management, however, remains poor in routine clinical practice. An Asthma UK survey estimated that only 24% of people with asthma currently have a PAAP.[12] The National Review of Asthma Deaths identified lack of PAAPs as a key preventable factor in the deaths that they investigated.[13] Identified barriers to implementing asthma self-management support are practical (e.g., time, no available paper-based PAAPs [14]); conceptual (e.g., mismatch between professionals' focus on clinical action plans and the advice patients want about 'living with asthma' [11]); and organisational (e.g. professional communication between nurses who provide self-management education and general practitioners (GPs) who treat exacerbations [15]). The systematic review of implementation studies conducted as part of PRISMS concluded that integration into routine practice required a whole systems approach in which motivated, skilled professionals support activated, informed patients within an organisation that values, promotes and monitors supported self-management.[16] We are undertaking preliminary work to develop, refine and evaluate the clinical and costeffectiveness of a practice-based intervention to implement self-management support for asthma in routine clinical practice in a UK-wide cluster RCT. Self-management support is defined as a service intervention that aims to empower patients to be active decision makers who deal with the emotional, social and medical management of their illness and improve their independence and quality of life. [5] An educational package for professionals who support people with asthma to self-manage will form a key component of the whole systems

approach. Professional education is a pre-requisite for effective implementation of supported

self-management and will not only need to address the skills required by the professionals

providing self-management education (typically asthma-trained general practice nurses in the UK) but also other members of the primary healthcare team providing services for people with asthma (including GPs, reception staff, prescribing clerks, and community pharmacists).[10]

The aim of this systematic review is therefore to inform the development of the educational package by synthesising the evidence regarding the effectiveness of educational interventions for professionals involved in supporting self-management. The review will focus on diabetes as well as asthma in order to go beyond existing interventions in asthma and learn from professional education approaches in another condition where selfmanagement support is well evidenced and often incentivised as fundamental to care. These two conditions have the most robust evidence base for the effectiveness of implementing supported self-management,[10] A comparison of self-management interventions in asthma and type 2 diabetes found that while interventions in asthma focussed on halting development of symptoms, studies in diabetes focussed on integrating regimens into patients' lifestyles: self-management support interventions for type 2 diabetes therefore tended to be broader than those for asthma.[17] Additionally, education for professionals on how to support self-management is key for the success of type 2 diabetes self-management support.[10] Consequently, there may be valuable lessons to learn for professional education in asthma self-management support through comparing and contrasting the literature for the two conditions.

#### **METHODS AND ANALYSIS**

 We will follow systematic review procedures described in the Cochrane Handbook for Systematic Reviews of Interventions.[18] The Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P) checklist has been used to guide the reporting of this protocol.[19] If amendments to the protocol are made, the description of each amendment will be reported along with the amendment number and date. The review commenced on 2<sup>nd</sup> November 2015 and will be completed by 30<sup>th</sup> September 2016.

# Eligibility criteria

# **Participants**

The target population is professionals providing care to people with asthma or Type 1 or Type 2 Diabetes Mellitus. This includes doctors, nurses, and health educators. Since the overarching purpose of the review is to inform the development of a primary care-based team intervention, primary care practice teams (including clinicians and administrative staff) are of particular interest. In this context, a primary care practice team is a team of professionals working within a community-based practice to provide patient care. Others who may support self-management in this context (such as pharmacists or lay/peer educators) will be included if their role is integrated within a primary care practice team, but excluded if the intervention did not involve the primary care team.

#### Interventions

Interventions of interest are educational packages designed to train professionals and/or practice teams to provide education to or support self-management in people with asthma or diabetes. These can comprise 14 components (information about condition/management; information about resources; plan/medication provision; regular review; monitoring and feedback; adherence support; equipment provision; access to advice/support; training/rehearsal for: communication with health-care professionals, everyday activities, practical self-management activities, psychological strategies; social support; and lifestyle advice and support).[20]

# Comparators

In most trials of educational interventions, the comparator will be 'no education', though some may compare components of an educational package (for example, different modes of delivery, such as online vs. face-to-face). The nature of the control service will be noted and accommodated within the analysis.

#### Outcomes

As this is a review of implementation-level interventions (i.e. interventions aimed at changing health outcomes through changes in clinical practice), the primary outcomes of interest are categorised into two levels: process-level outcomes, and health outcomes. Process-level outcomes reflect professional behaviour change. The primary process-level outcomes are the proportion of people with asthma receiving PAAPs, and the proportion of people with diabetes receiving structured education.

The ATS/ERS Task Force report on asthma outcome assessment recommended that health outcomes in trials should reflect measures of both current control and future risk.[21] To maintain consistency, we have applied this recommendation to the selection of primary health outcomes for both asthma and diabetes in this review. The primary outcomes representing current control are markers of asthma control (asthma control questionnaire or similar validated questionnaire), and HbA1c level for diabetes. The primary outcomes representing future risk are the proportion of people with an unscheduled consultation for acute asthma deterioration (e.g. out-of-hours/ GP consultation/ A&E/ admission), and acute events related to diabetic control and necessitating urgent action (e.g. hypoglycemia/ hyperglycemia/ diabetic ketoacidosis).

To ensure that our outcomes reflect the broad view of self-management support as encompassing the emotional, social and medical management of illness, secondary outcomes comprise behavioural/cognitive measures related to both professionals (e.g. improvement in communication skills, confidence, competence) and patients (e.g. self-efficacy, empowerment, and activation) and other measures of control (e.g. symptom free days) or future risk (e.g. exacerbations/ steroid courses). When extracting secondary outcome data, outcomes assessed using validated tools will be prioritised.

Study design

194	Randomised controlled trials and controlled clinical trials will be included, since educational
195	interventions many not always be evaluated in randomised controlled trials.

#### Setting

- Any healthcare setting is of interest, though trials implemented within primary care teams will be of particular interest.
  - Years considered
- Studies published from 1990 onwards will be included, as evolving professional educational approaches mean that earlier literature is unlikely to be relevant.
- 202 Language
- There will be no language restrictions for included studies: literature will be translated where possible, and any literature that we are unable to translate will be reported.

#### Information sources

Electronic searches will be conducted in CENTRAL, MEDLINE, EMBASE, ISI Web of Science, CINAHL, PsycINFO, AMED, Global Health, WHO Global Health Library, ERIC, BNI, RDRB/CME, and Google Scholar for studies published from 1990 until 2016. For all included studies, reference lists will be scrutinised and prospective citation tracking will be performed to identify additional relevant studies, including any qualitative work associated with included studies that may be helpful for providing further insights into our findings. We are not aware of any specific journals specialising in this literature which may require hand-searching: however, if such journals become apparent after gathering relevant studies, these will be hand-searched.

To identify relevant unpublished and in-progress studies, key internet-based relevant databases will be searched (UK Clinical Research Network Study Portfolio; the meta Register of Controlled Trials, www.clinicaltrials.gov; and www.controlled-trials.com).

218 Relevant qualitative studies which inform educational interventions (e.g., published

alongside trials)[22] will be retrieved. Authors of included studies will be contacted to i) source further published or unpublished results and/or training manuals related to their study if available; ii) source other relevant published, unpublished or ongoing studies including any related qualitative work.

We will supplement the published literature review by undertaking a scoping exercise of existing potentially relevant packages in asthma and diabetes through: i) searching English language policy literature and health service websites for information about improvement initiatives involving up-skilling practices/clinical teams to improve self-management; and ii) contacting the initiative leads for information about the packages.

# Search strategy

A sensitive search strategy has been developed following advice from a senior librarian (Marshall Dozier, University of Edinburgh) using the Ovid interface for MEDLINE (Supplementary File). This will be adapted for searches in other databases.

# **Data management**

Literature search results will be exported to EndNote Library, which will be used for deduplication, study screening, and overall management of the retrieved records. Microsoft Word will be used to develop a data extraction form, which will be piloted and refined before use. Data will be extracted and stored electronically. Multiple reports from the same study will be treated as a single study, but we will draw on and make reference to all relevant publications.

#### **Selection process**

One reviewer (NM) will undertake an initial filter of duplicates and clearly irrelevant titles.

Before title and abstract screening begins, two reviewers (NM and AA) and the joint project leads (HP and ST) will independently screen a sample of 100 titles and abstracts from the searches for inclusion according to the review criteria in order to clarify interpretation of

 inclusion/exclusion criteria and as a quality control check. Any disagreements will be resolved by discussion and consultation with the project team, if required. This process will be repeated on further samples of 100 titles and abstracts until the level of agreement between all reviewers is deemed satisfactory (≥ 90%). The two reviewers will then independently screen all titles and abstracts, selecting potentially eligible papers for full text screening. The full texts of all potentially eligible studies will be retrieved and independently screened by the two reviewers. Disagreements at both stages will be resolved by discussion, or arbitration by a third reviewer (HP or ST) if necessary. If after the full text assessment it is still unclear whether a study fulfils the inclusion criteria, the study authors will be contacted by email for clarification: if this fails, the respective study will be listed as a 'potentially relevant study'. The searching and screening processes will be summarised using a PRISMA flow diagram.[23]

#### Data collection process

The two reviewers (NM and AA) will extract the main findings from each study onto the data extraction form. The form will be piloted on a sub-sample of included studies to ensure it is easily and consistently interpreted and captures all relevant information. Data extraction disagreements will be resolved by discussion, or arbitration by a third reviewer (HP or ST) if necessary.

#### **Data items**

Data will be extracted relating to general study characteristics, participant characteristics, details of the intervention and control conditions, the relevant outcomes assessed and corresponding results, and information for assessment of the risk of bias.

# Risk of bias in individual studies

The two reviewers (NM and AA) will conduct independent assessments of methodological quality and risk of bias using the Cochrane Risk of Bias Tool.[24] Disagreements will be resolved by discussion or, if necessary, arbitration by a third reviewer (HP or ST). The

resulting risk of bias in included studies will be used to evaluate the robustness of the findings.

## Data synthesis

Descriptive tables will be used to summarise the characteristics of included studies. Frameworks such as TIDieR (a template for reporting interventions)[25] and/or the Theoretical Domains Framework (a validated framework that identifies domains of theoretical approaches to behaviour change interventions which has been applied retrospectively to published interventions)[26-28] will be used to describe the interventions. On a practical level, in order to inform the development of the educational component for our proposed implementation intervention, we will also take into account any frameworks used by Education for Health in the development of their courses. A detailed descriptive summary of studies will be compiled, including data under the headings of: setting (primary/secondary care); at whom the intervention is directed (individual professional, groups, practice teams); mode of delivery (group, individual, face-toface, on-line); components (lectures, workshops, assignments, practical skills, mentorship); duration and intensity of education/mentoring, generic/disease focused, outcomes assessed, information about uptake and any information about fidelity. We may undertake some short telephone interviews with authors in order to enhance our understanding of the interventions. Based on preliminary scoping work, it is anticipated that there will be substantial heterogeneity so that meta-analysis will not be appropriate. A narrative synthesis of the aggregate data will therefore be undertaken. This will be achieved by developing a matrix of what has been shown to be effective/ineffective and the elements of the educational package (including content, mode of delivery, duration, intensity). Depending on the available data, graphical techniques (e.g. Harvest plots [29]) may be used to illustrate key

outcomes and their relationship to these elements.

 Although the overall pool of included studies are likely to be heterogeneous in nature, metaanalyses may be appropriate for sub-sets of studies with limited heterogeneity. For example,
Cochrane reviews of professional education approaches have found that process-level
outcomes are more often evaluated than patient health outcomes:[30-31] meta-analyses of
some process-level outcomes may therefore be possible. Where appropriate, randomeffects meta-analysis models for subsets of studies will be used, to take into account
potential heterogeneity between studies.[32] Heterogeneity will be quantified using the I<sup>2</sup>
statistic.

Qualitative data will be used to enhance our understanding of participants' perceptions of the impact of participating in the educational intervention on their professional practice. Data from qualitative studies will be synthesised thematically.[33] An overarching narrative synthesis of quantitative and qualitative findings will be undertaken.[34] Depending on the extent of the literature available in the different disease areas, sub-group analyses may be undertaken according to the targeted professionals (doctor, nurse, practice team) and/or setting (primary/secondary care). The findings of the scoping exercise of existing potentially relevant packages in asthma and diabetes will be used to supplement those of the systematic review.

The multidisciplinary research team, the wider project team and the steering group will meet regularly to discuss the emerging findings and aid interpretation. The PRISMA checklist will be used to guide reporting of the review.[23]

# **REGISTRATION**

The protocol for this review has been registered with the International Prospective Register of Systematic Reviews (PROSPERO; 2016:CRD42016032922).

## **ETHICS AND DISSEMINATION**

Ethical approval is not required for this study, given that it is a systematic review utilising data already in the public domain. This review will inform the educational component of a

whole systems intervention that will help primary care practice teams embed supported self-management into routine asthma care. A paper describing the review will be submitted for peer-reviewed publication. The infrastructure of the Asthma UK Centre for Applied Research (AUKCAR) will be used to support innovative approaches to dissemination (e.g. via social media and Science Festivals).

#### CONCLUSION

Whilst patient education, professional training and organisational support are all essential components of successful self-management support, they are rarely effective in isolation.[10] Effective implementation is multi-faceted and multidisciplinary: it involves engaging patients and training and motivating professionals within the context of an organisation which actively supports self-management.[10, 16] This review will achieve clarity on educational strategies likely to be effective in enabling professionals to implement supported self-management in their clinical practice, and will inform the development of an educational package which will serve as one component of a whole systems intervention aiming to embed supported self-management into routine primary care asthma management.

### **REFERENCES**

- Asthma UK. Asthma facts and statistics. Available from http://www.asthma.org.uk/asthma-facts-and-statistics (accessed Feb 2016)
- British Thoracic Society/Scottish Intercollegiate Guideline Network. British Guideline
  on the Management of Asthma: 2014 update. *Thorax* 2014;69(Suppl1):1-192.
   Available from <a href="http://www.sign.ac.uk">http://www.sign.ac.uk</a> (accessed Feb 2016)
  - Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2014. Available from <a href="http://www.ginasthma.org">http://www.ginasthma.org</a> (accessed Feb 2016)
- Gibson PG, Powell H, Wilson A, et al. Self-management education and regular practitioner review for adults with asthma. *Cochrane Database of Systematic Reviews* 2002, Issue 3. Art.No:CD001117

347	5.	Adams K, Greiner AC, Corrigan JM. Eds. The 1st Annual Crossing the Quality
348		Chasm Summit – A Focus on Communities. Washington, DC: The National
349		Academic Press 2004:57
350	6.	Tapp S, Lasserson TJ, Rowe BH. Education interventions for adults who attend the
351		emergency room for acute asthma. Cochrane Database of Systematic Reviews
352		2007, Issue 3. Art.No:CD003000
353	7.	Gibson PG, Powell H. Written action plans for asthma: an evidence-based review of
354		the key components. Thorax 2004;59:94–99
355	8.	Toelle B, Ram FSF. Written individualised management plans for asthma in children
356		and adults. Cochrane Database of Systematic Reviews 2004, Issue 1.
357		Art.No:CD002171
358	9.	Lefevre F, Piper M, Weiss K, et al. Do written action plans improve patient outcomes
359		in asthma? An evidence-based analysis. J Fam Prac 2002;51:842–848
360	10	. Taylor SJC, Pinnock H, Epiphaniou E, et al. A rapid synthesis of the evidence on
361		interventions supporting self-management for people with long-term conditions.
362		(PRISMS Practical Systematic Review of Self-Management Support for long-term
363		conditions) Health Serv Deliv Res 2014;2:54
364	11	. Ring N, Jepson R, Hoskins G, et al. Understanding what helps or hinders asthma
365		action plan use: a systematic review and synthesis of the qualitative literature. Pat Ed
366		Counsel 2011;85:e131–e143
367	12	. Asthma UK. <i>Time to take action on asthma</i> . Available from
368		https://www.asthma.org.uk/globalassets/campaigns/compare-your-care-2014.pdf
369		(accessed Feb 2016)
370	13	. Royal College of Physicians. Why asthma still kills: the National Review of Asthma
371		Deaths (NRAD) Confidential Enquiry report. London: RCP 2014
372	14	. Wiener-Ogilvie S, Pinnock H, Huby G, et al. Do practices comply with key
373		recommendations of the British Asthma Guideline, and if not, why not? Prim Care
374		Resp J 2007;16:369-377
		15

375	15. Weiner-Ogilvie S, Huby G, Pinnock H, et al. Practice organisational characteristics
376	can impact on compliance with the BTS/SIGN asthma guideline: qualitative
377	7 comparative case study in primary care. <i>BMC Fam Pract</i> 2008;9:32
378	16. Pinnock H, Epiphaniou E, Pearce G, et al. Implementing supported self-managemen
379	for asthma: a systematic review of implementation studies. <i>BMC Med</i> 2015;13:127
380	17. Newman S, Steed L, Mulligan K. Self-management interventions for chronic illness.
38	1 Lancet 2004;364(9444):1523-1537.
382	18. Higgins JPT, Green S. Eds. Cochrane Handbook for Systematic Reviews of
383	Interventions. Version 5.1.0 [updated March 2011]. The Cochrane Collaboration,
384	2011. Available from <a href="http://handbook.cochrane.org/">http://handbook.cochrane.org/</a> (accessed Feb 2016)
38	19. Shamseer L, Moher D, Clarke M, et al. Preferred reporting items for systematic
386	review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation.
387	7 BMJ 2015;349:g7647
388	20. Pearce G, Parke H, Pinnock H, et al. The PRISMS taxonomy of self-management
389	support: derivation of a novel taxonomy and initial testing of utility. J Health Serv Res
390	Policy 2015:1355819615602725[Epub ahead of print]
39	21. Reddel HK, Taylor DR, Bateman ED, et al. An Official American Thoracic
392	Society/European Respiratory Society statement: asthma control and exacerbations
393	standardizing endpoints for clinical asthma trials and clinical practice. Am J Respir
394	4 Crit Care Med 2009;180:59–99
398	22. Barnett-Page E, Thomas J. <i>Methods for Research Synthesis Node</i> . Evidence for
396	Policy and Practice Information and Co-ordinating (EPPI-)Centre, Social Science
397	Research Unit, Institute of Education. Available from
398	http://eppi.ioe.ac.uk/cms/Default.aspx?tabid=188 (Accessed Feb 2016)
399	23. Moher D, Liberate A, Tetzlaff J, et al. Preferred Reporting Items for Systematic
400	Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med
401	1 2009;6(7):e1000097
	16

402	24. Higgins JPT, Altman DG, Sterne JAC, on behalf of the Cochrane Statistical Methods
403	Group and the Cochrane Bias Methods Group. Chapter 8: Assessing risk of bias in
404	included studies. Available from
405	http://handbook.cochrane.org/chapter 8/8 assessing risk of bias in included studi
406	es.htm (Accessed Feb 2016)
407	25. Hoffmann T, Glasziou P, Boutron I, et al. Better reporting of interventions: template
408	for intervention description and replication (TIDieR) checklist and guide. BMJ
409	2014;348:g1687
410	26. Michie S, Johnston M, Abraham C, et al. Making psychological theory useful for
411	implementing evidence based practice: a consensus approach. Qual Saf Health Care
412	2005;14:26-33
413	27. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for
414	use in behaviour change and implementation research. Implement Sci 2012;7:37
415	28. Little EA, Presseau J, Eccles MP. Understanding effects in reviews of implementation
416	interventions using the Theoretical Domains Framework. Implement Sci 2015;10:90
417	29. Ogilvie D, Fayter D, Petticrew M, et al. The harvest plot: a method for synthesising
418	evidence about the differential effects of interventions. BMC Med Res Methodol
419	2008;8:8
420	30. Giguère A, Légaré F, Grimshaw J, et al. Printed educational materials: effects on
421	professional practice and healthcare outcomes. Cochrane Database of Systematic
422	Reviews 2012, Issue 10. Art.No:CD004398
423	31. O'Brien MA, Rogers S, Jamtvedt G, et al. Educational outreach visits: effects on
424	professional practice and health care outcomes. Cochrane Database of Systematic
425	Reviews 2007, Issue 4. Art.No:CD000409
426	32. Borenstein M, Hedges LV, Higgins JPT, et al. A basic introduction to fixed-effect and
427	random-effects models for meta-analysis. Res Synth Methods 2010;1(2):97–111
428	33. Thomas J, Harden A. Methods for the thematic synthesis of qualitative research in
429	systematic reviews. BMC Med Res Methodol 2008;8:45
	17

430	34. Ring N, Jepson R, Pinnock H, et al. Developing novel evidence-based interventions
431	to promote asthma action plan use: a cross-study synthesis of evidence from
432	randomised controlled trials and qualitative studies. Trials 2012;13:216
433	ACKNOWLEDGEMENTS
434	The authors thank Marshall Dozier, Senior Liaison Librarian and Liaison Director for the
435	College of Medicine and Veterinary Medicine at the University of Edinburgh, who assisted in
436	developing the search strategy.
437	AUTHORS' CONTRIBUTIONS
438	HP and ST conceived the idea for this work and are the guarantors. The protocol was
439	drafted by NM and was then revised after several rounds of critical comments and additional
440	feedback from AA, SM, SW-O, MF, LS, ST and HP. All authors will be involved in the
441	systematic review process.
442	The IMP <sup>2</sup> ART team also includes Aziz Sheikh, Brian McKinstry, and Luke Daines (University
443	of Edinburgh); Chris Griffiths and Sandra Eldridge (Queen Mary University of London);
144	Anne-Louise Caress (University of Manchester); Elisabeth Ehrlich (Asthma UK Centre for
445	Applied Research); Bethan Haskins (Canterbury and Coastal Clinical Commissioning
446	Group); Rob Horne (University College London); Steven Julious (University of Sheffield);
447	Lorna McKee (University of Aberdeen); and Ceri Phillips (University of Swansea).
448	COMPETING INTERESTS
449	Monica Fletcher is the Chief Executive for Education for Health, an organisation that
450	provides training for healthcare professionals. The authors declare no further competing
451	interests related to this work.
452	FUNDING
453	This report is independent research funded by the National Institute for Health Research
454	(Programme Development Grants, Implementing supported asthma self-management in

routine clinical care: designing, refining, piloting and evaluating a whole systems implementation within an MRC Phase IV programme of research, RP-DG-1213-10008). The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health. This work is sponsored by the University of Edinburgh. The funder and sponsor have not had any role in developing the protocol.

#### SUPPLEMENTARY FILE

### **MEDLINE Search Strategy**

- 1. Primary Health Care/ or Family Practice/ or General Practice/
- 2. (primary care or primary medical care or primary health care or primary healthcare or general practice or family practice).mp.
- 3. Health Personnel/ or Medical Staff/
- 4. ((healthcare or health care) adj3 (provider? or practitioner? or professional?)).mp.
- Physicians/ or Physicians, Primary Care/ or Physicians, Family/ or General Practitioners/
- 6. (general practitioner? or medical practitioner? or physician? or clinician? or doctor? or GP?).mp.
- 7. Nurses/ or Nursing Staff/ or Nurse Practitioners/ or Family Nurse Practitioners/
- 8. (nurse? or practice nurse? or community nurse? or nurse practitioner?).mp.
- 9. Medical Secretaries/ or Medical Receptionists/
- 10. (secretar\$ or reception\$ or administrat\$).mp.
- 11. Pharmacists/
- 12. pharmacist?.mp.
- 13. Health Educators/
- 14. health educator?.mp.
- 15. Patient Care Team/
- 16. ((primary care or primary care practice or health care or healthcare or medical care or general practice or family practice) adj3 team?).mp.
- 17. or/1-16
- 18. Education/ or Health Education/
- 19. (educat\$ or train\$).mp.
- 20. (skill? adj3 develop\$).mp.
- 21. Education, Professional/ or Education, Continuing/
- 22. (professional development or CPD).mp.
- 23. ((interprofessional or inter-professional) adj3 (educat\$ or train\$ or develop\$ or skill?)).mp.
- 24. ((team? or group?) adj3 (educat\$ or train\$ or develop\$ or skill?)).mp.
- 25. Education, Medical/ or Education, Medical, Continuing/
- 26. (continuing medical education or CME).mp.
- 27. Education, Nursing/ or Education, Nursing, Continuing/ or Nursing Education Research/ or Nursing Evaluation Research/
- 28. Education, Pharmacy/ or Education, Pharmacy, Continuing/
- 29. Quality Improvement/
- 30. (quality adj3 improv\$).mp.
- 31. or/18-30
- 32. Disease Management/
- 33. disease management.mp.
- 34. Self Care/ or Self Administration/ or Self Medication/
- 35. (self-manag\$ or selfmanag\$ or self-car\$ or selfcar\$ or self-help or selfhelp or self-administrat\$ or selfadministrat\$ or self-monitor\$ or selfmonitor\$ or self-medicat\$ or selfmedicat\$).mp.
- 36. (self adj3 (manag\$ or car\$ or help or administrat\$ or monitor\$ or medicat\$)).mp.
- 37. Quality of Health Care/
- 38. (quality adj3 (care or healthcare or health care)).mp.
- 39. Professional-Patient Relations/ or Physician-Patient Relations/ or Nurse-Patient Relations/

- 40. (patient? adj3 (relation\$ or communicat\$)).mp.
- 41. ((action or treat\$ or car\$ or written or manag\$ or medicat\$) adj3 plan\$).mp.
- 42. ((self-manag\$ or self manag\$ or selfmanag\$ or self-car\$ or self car\$ or selfcar\$ or self-help or self help or selfhelp or self-administrat\$ or self administrat\$ or self-monitor\$ or selfmonitor\$ or selfmonitor\$ or self-medicat\$ or self medicat\$ or selfmedicat\$ or self-treat\$ or self treat\$ or selftreat\$) adj3 plan\$).mp.
- 43. (exacerbat\$ or attack?).mp.
- 44. asthma control test.mp.
- 45. Hospitalization/
- 46. hospitali?ation?.mp.
- 47. After-Hours Care/
- 48. (out of hours or out-of-hours or OOH).mp.
- 49. Office Visits/
- 50. ((office or hospital or emergency department or ED or A&E or A & E or "accident and emergency") adj3 (visit\$ or refer\$ or admission\$)).mp.
- 51. ((care or service?) adj3 (utili?ation or use?)).mp.
- 52. Patient Education/
- 53. Blood Glucose Self Monitoring/
- 54. Hemoglobin A, Glycosated/
- 55. HbA1c.mp.
- 56. Hypoglycemia/ or Hyperglycemia/
- 57. Diabetic Ketoacidosis/ or Hyperglycemic Hyperosmolar Nonketotic Coma/
- 58. (hyperosmolar hyperglyc?emic nonketotic syndrome or DKA or HNNS or HONK).mp.
- 59. glyc?emic control.mp.
- 60. or/32-59
- 61. Asthma/
- 62. (asthma or wheez\$).mp.
- 63. (antiasthma\$ or anti-asthma\$).mp.
- 64. Respiratory Hypersensitivity/
- 65. ((bronchial\$ or respiratory or airway\$ or lung\$) adj3 (hypersensitive\$ or hyperreactiv\$ or allerg\$ or insufficiency)).mp.
- 66. Bronchial Spasm/
- 67. Bronchoconstriction/
- 68. (bronch\$ adj3 (constrict\$ or spas\$)).mp.
- 69. (bronchoconstrict\$ or bronchospas\$).mp.
- 70. bronchial hyperreactivity.mp.
- 71. respiratory sounds.mp.
- 72. Diabetes Mellitus/
- 73. diabet\$.mp.
- 74. Diabetes Mellitus, Type 1/
- 75. ((diabet\$ or dm) adj5 (typ\$ adj3 (one or "1" or I))).mp.
- 76. Diabetes Mellitus, Type 2/
- 77. ((diabet\$ or dm) adj5 (typ\$ adj3 (two or "2" or II))).mp.
- 78. Insulin Resistance/
- 79. ((insulin or noninsulin or non-insulin) adj3 (resistan\$ or depend\$)).mp.
- 80. (DM or DM1 or DM2 or T1D or T1DM or T2D or T2DM or NIDDM or IDDM or MODY).mp.
- 81. glucose \$tolerance.mp.
- 82. or/61-81
- 83. Pragmatic Clinical Trial/ or Clinical Trial/ or Randomized Controlled Trial/ or Controlled Clinical Trial/

- 84. randomi?ed controlled trial.pt.
- 85. controlled clinical trial.pt.
- 86. (randomi?ed or randomly).ti,ab.
- 87. trial.ti,ab.
- 88. group?.ti,ab.
- 89. or/83-88
- 90. 17 and 31 and 60 and 82 and 89
- 91. (letter or review or comment or editorial).pt.
- 92.90 not 91
- 93. (Animals/ or Nonhuman/) not Humans/
- 94. 92 not 93

*Note:* a free-text term related to professional behaviour (prof\$ adj3 behav\$).mp.) was considered for inclusion in section two of the above search, which is focussed on educational interventions. However, it was not included because when added, it did not retrieve any records additional to those already retrieved.

 This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 3 in Moher D et al: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 **4**:1

Cootion/tonio	л.	Checklist item	Information reporte		Line
Section/topic	#	Checklist item	Yes	No	number(s)
ADMINISTRATIVE IN	FORMAT	TION <u>§</u>			
Title		oade			
Identification	1a	Identify the report as a protocol of a systematic review			2
Update	1b	If the protocol is for an update of a previous systematic review, identify as such			N/A
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract			62
Authors		ope ope			
Contact	3а	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author			a-21 e-mail address provided for corresponding author only, per journal instructions
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review			438-441
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments			141-142
Support		st. P			
Sources	5a	Indicate sources of financial or other support for the review			453-460
Sponsor	5b	Provide name for the review funder and/or sponsor			453-460
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocology			453-460
	50	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocolog			

		BMJ Open  BMJ Open				Page 2
Section/topic #		Checklist item		Informatio Yes	n reported No	Line number(s)
INTRODUCTION		n 28				
Rationale 6						75-136
Objectives 7		Describe the rationale for the review in the context of what is already known  Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)				121-126
METHODS		0 W1				
Eligibility criteria 8		Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review				145-204
Information sources 9		Describe all intended information sources (e.g., electronic databases, contact with study authorized registers, or other grey literature sources) with planned dates of coverage	s,			206-227
Search strategy 10	0	Present draft of search strategy to be used for at least one electronic database, including plannlimits, such that it could be repeated	ed			229-231 & supplementary file
STUDY RECORDS						
Data management 1	1a	Describe the mechanism(s) that will be used to manage records and data throughout the review	v			233-238
Selection process 1	1b	State the process that will be used for selecting studies (e.g., two independent reviewers) three each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	gh			240-255
Data collection process	1c	Describe planned method of extracting data from reports (e.g., piloting forms, done independent in duplicate), any processes for obtaining and confirming data from investigators	tly,			257-261 219-227
Data items 12	2	List and define all variables for which data will be sought (e.g., PICO items, funding sources), pre-planned data assumptions and simplifications	ny			263-265
Outcomes and prioritization	3	List and define all outcomes for which data will be sought, including prioritization of main and gadditional outcomes, with rationale				169-192
Risk of bias in individual studies	4	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used data synthesis	า			267-271
DATA		copyright.				



1	
2	
3	
4	
5	
6	
7	
6 7 8	
0	
1	0
1	1
1	2
1	3
1	4
1	5
1	6
1	7
1	R
1	9
2	n
2	1
2	2
2	ィ
2	1
2	0123456789012345678901234567
2	s S
2	7
2	ı Ω
2	a
2	S O
ა ი	4
ა ი	1
ა ი	2
3	ა ⊿
3	4
3	5
3	0
3	7 8
3	ŏ
3	9
4	0
4	1
4	
4	
4	
4	-
4	
4	7

25 of 25		BMJ Open	bmiopen-2016-011937			
Section/topic	#			Informatio Yes	n reported No	Line number(s)
	15a		on 28			288-302
Synthesis	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methof handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., $I^2$ , Kendall's tau)	eds Son			299-302
	15c		2016. D			306-309
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	Down			289-314
Meta-bias(es)	16		ed			N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	from h			N/A
			from http://bmiopen.bmi.com/ on April 18. 2024 by guest. Protected by copyright.		Piol	<b>Vled</b> Centr