FULL/LONG TITLE OF THE STUDY

Identifying health literacy interventions that reduce the use of primary care and emergency services for minor problems: a systematic review.

SHORT STUDY TITLE / ACRONYM

Health literacy interventions / HLI

PROTOCOL VERSION NUMBER AND DATE

Version 0.1, 14/10/2020

RESEARCH REFERENCE NUMBERS

IRAS Number:	Not applicable
PROSPERO REG:	CRD42020214206
SPONSORS Number:	165003
FUNDERS Number:	NIHR131238

DISCLAIMER

This study/project is funded by the National Institute for Health Research (NIHR) [Health Services and Delivery Research] (project reference: NIHR131238/ HS&DR). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Jennifer Burr

Date:
...04/11/2020

....

Name (please print):

Dr Jennifer Burr...

Position:
Senior University Teacher...

Chief Investigator:

Signature: Alicia O'C

Date:
7/10/20

....

Name: (please print): Alicia O'Cathain

....

LIST of CONTENTS

KEY STUDY CONTACTS

Chief Investigator	Prof. Alicia O'Cathain ScHARR University of Sheffield Regent Street Sheffield S1 4DA UK Tel. +44 114 222 0770 a.ocathain@sheffield.ac.uk
Study Co-ordinator	Dr. Alexis Foster ScHARR University of Sheffield Regent Street Sheffield S1 4DA UK Tel. +44 114 222 6129 alexis.foster@sheffield.ac.uk
Sponsor	The University of Sheffield Research Office Western Bank Sheffield, S10 2TN UK
Joint-sponsor(s)/co-sponsor(s)	NA
Funder(s)	National Institute for Health Research (NIHR) Health Services and Delivery Research
Key Protocol Contributors	Dr. Alexis Foster ScHARR University of Sheffield Regent Street Sheffield S1 4DA UK Tel. +44 114 222 6129 alexis.foster@sheffield.ac.uk Dr. Joanne Protheroe Keele Medical School Primary Care Centre Versus Arthritis Faculty of Medicine and Health Sciences Keele University Staffordshire, ST5 5BG Tel. + 44 1782 734698 Email: j.protheroe@keele.ac.uk

	Dr. Louise Preston Senior Research Fellow, ScHARR The University of Sheffield Regent Street Sheffield S1 4DA UK Tel. +44 114 222 0847 Email: l.r.preston@sheffield.ac.uk Miss Margaret Elizabeth Ogden PPI Co-applicant Contactable via Alexis Foster
Committees	NA

STUDY SUMMARY

Study Title	Identifying health literacy interventions that reduce the use of primary care and emergency services for minor problems: a systematic review.
Internal ref. no. (or short title)	NIHR131238
	An important complementary approach to current national initiatives to manage demand for primary and emergency services is intervention further back in the pathway of help-seeking behaviour. That is, it may be possible to reduce population need to seek advice from primary and emergency services for minor health problems (preventing 'entry access'), and thereby reducing demand for these pressurised services. Health literacy may reduce the perceived need for contacting a health service, the perceived urgency of the problem, or improve ability to identify and choose from the range of available services. Interventions to improve health literacy exist, with variable findings about effectiveness at reducing use of primary and emergency services. We want to undertake a systematic review of this evidence to identify the effectiveness, cost-effectiveness and safety of interventions; understand the mechanisms of action of effective interventions and the contexts in which they work; and describe in detail successful and cost-effective interventions relevant to the UK context. We will hold two Stakeholder Events, the first one to inform the review, and the second to identify how best to implement cost-effective interventions using the FAME framework of feasibility, appropriateness, meaningfulness and effectiveness.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
National Institute for Health Research (NIHR) Health Services and Delivery Research	Financial Support

ROLE OF STUDY SPONSOR AND FUNDER

They will not be involved in the research.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Professor Alicia O'Cathain will lead the project. There will be a project management team meeting every two months involving all team members to review progress and plan the next set of actions. Dr Louise Preston will supervise the work of the Information Specialist and Research Fellow Reviewer (these three team members will meet fortnightly). Dr Alexis Foster will lead the stakeholder involvement.

KEY WORDS: Health literacy, emergency care, primary care

STUDY GANTT CHART

The review will be completed in 13 months

Months	Oct 20	Nov-20	Dec-20	Jan 21	Feb 21	Mar 21	Apr 21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21
Project months	-1	1	2	3	4	5	6	7	8	9	10	11	12	13
Admin/events														
Recruitment of Research Fellow	■													
Set-up shared electronic spaces	■													
Project management team meetings		■	■		■		■		■		■		■	■
PPI meetings (likely – need to be flexible)		■		■				■	■				■	■
Stakeholder Events		■									■	■		
Systematic review														
Protocol submitted to PROSPERO			■											
Searching			■	■				■	■					
Screening				■	■	■		■	■					
Data extraction						■	■	■	■					
Quality Assessment						■	■	■	■					
Synthesis									■	■		■	■	■
Reports														
Interim report								■						
Final report														■

STUDY PROTOCOL

Identifying health literacy interventions that reduce the use of primary care and emergency services for minor problems: a systematic review

1 BACKGROUND

Pressure on primary and emergency care in the UK

There is considerable pressure on general practices, emergency departments and emergency ambulances in the UK. In 2019 the Royal College of General Practitioners highlighted ‘intense resource and workforce pressure' on GP out-of-hours services (www.rcgp.org.uk (a)) and expressed concerns about decreases in the numbers of GPs per head of population despite rising demand for general practice (www.rcgp.org.uk (b)). On the NHS England website, policy makers estimate that there are 110 million urgent patient contacts in England each year, with around 85 million being same-day GP appointments, and the rest attendances at emergency departments and minor injury units (www.england.nhs.uk (a)). They estimate that between 1.5 and 3 million attendances at emergency departments could be addressed in other parts of the urgent care system.

Policy makers and service providers attempt to manage increasing demand by introducing new initiatives. They tend to focus largely on service and workforce reconfiguration that offer alternatives to the three pressurised services, or on interventions to manage minor problems efficiently within each of these three services. Examples of these initiatives include walk-in centres, GPs working in emergency departments, and paramedics working in general practices. Initiatives also include interventions aimed at changing population behaviour so that people self-care when appropriate and attend the right service for their need. These initiatives include encouraging patients to use online diagnostic tools such as NHS Online or the national telephone helpline NHS 111 for urgent care. An important complementary approach to these initiatives is intervention further back in the pathway of help-seeking behaviour. That is, it may be possible to reduce population need to seek advice from primary and emergency services for minor problems, (preventing clinically unnecessary ‘entry access’), and thereby reducing demand for pressurised services. Health literacy may reduce the perceived need for contacting a health service, the perceived urgency of the problem, or improve ability to identify and choose from the range of available services.

2 RATIONALE

What is health literacy?

The World Health Organisation (WHO) defines health literacy as: "….the personal characteristics and social resources needed for individuals and communities to access, understand, appraise and use information and services to make decisions about health" (www.england.nhs.uk (b)).

There are different types of health literacy: functional or basic health literacy (reading and writing skills), communicative health literacy (cognitive and social skills to extract information and apply it), and critical health literacy which requires more advanced cognitive and social skills to analyse information (Nutbeam 2009).

People with limited health literacy struggle with a number of issues including

- finding information,
- reading and understanding information,
- knowing how to act on information,
- knowing how to communicate with health professionals,
- and knowing which services to use and when (Osbourne et al 2013).

Health literacy has been viewed as an individual skill but increasingly the relevance of an individual's social support system (e.g. partner, family, community) and context (e.g. the healthcare system available) is viewed as important (Heijmans et al 2015).

How is heath literacy measured?

There are a number of validated measures of health literacy that either test health literacy (objective measures) or measure people's perceptions of their health literacy (subjective measures). Examples include the objective measure Newest Vital Sign used in a study of health literacy in parents attending a paediatric emergency department for non-urgent problems (Morrison et al 2014) and the subjective measure Health Literacy Questionnaire that measures multiple domains of health literacy (Osbourne et al 2015).

Different ways of thinking about health literacy (different paradigms)

Researchers often consider health literacy within what we term a 'public health/health inequalities' paradigm. Here, poor health literacy prevents care-seeking when needed, and stops people making healthy lifestyle choices, both of which can lead to poor health outcomes. The emphasis of interventions is on empowerment and increasing use of preventative health services. Interventions may also focus on self-management of chronic diseases that might lead to reductions in use of health care.

In this proposal we view health literacy in a different way. We consider health literacy within what we term a 'clinical risk' paradigm currently adopted by researchers in emergency care in the United States of America (USA). We are interested in the effect of health literacy on decisions to use primary and emergency services. That is, people with low health literacy have difficulty understanding clinical risk and therefore use primary and emergency services for minor health problems. In the 'clinical risk' paradigm the emphasis of interventions is on information, education and support to improve health literacy so people can make decisions about when and where to seek health care. The aim is to reduce use of health services for minor problems.

For clarification, when we use the term ‘public health paradigm’ does not mean ‘public health literacy’ where people make decisions that will benefit the wider community rather than the individual. We acknowledge that part of the ‘clinical risk paradigm’ might include educating people about the benefits to the population of keeping emergency services for emergencies which means forgoing what might be the most convenient option for an individual. In our ‘clinical risk paradigm’ we are not only interested in improving information and systems in NHS emergency services. Interventions can be delivered in a range of settings that build patient and public capacities to make informed decisions in relation to their primary and emergency care.

3 THEORETICAL FRAMEWORK

Evidence base on relationship between health literacy and use of primary and emergency services

There is evidence that lower health literacy is related to higher use of primary care including contacting a GP (van der Heide et al 2015), frequency of doctor visits (Berens et al 2018), and use of out of hours primary care services (Jansen et al 2018).

There is evidence that lower health literacy is associated with higher use of emergency services (Berkman et al 2011 (systematic review)) including higher unnecessary use of the ambulance service in Japan (Ueki et al 2019), emergency department use for minor or non-urgent problems in the USA (Schumacher et al 2013, Morrison et al 2014), and emergency department return rates (Griffey et al 2015). This relationship is not fully explained by educational status. Although health literacy is associated with educational attainment, 29% of people attending emergency departments for non-urgent issues were found to have a college education and low health literacy (Morrison et al 2014). Higher use of emergency services for minor problems by people with lower health literacy may be due to overestimating the severity of illness and seeking care sooner (May et al 2018).

A recent British population survey of demand for same day general practice, emergency ambulances, and emergency departments for minor health problems identified that people with lower health literacy had a higher tendency for contacting general practice and emergency ambulances in a multivariable analysis testing a wide range of 50 variables (O’Cathain et al, 2020).We believe that the relationship between health literacy and demand for emergency and primary care is clear and that a systematic review to establish this relationship is not necessary.

Evidence base for interventions to reduce use of primary and emergency care for minor problems

Below we describe the evidence base, which consists of no systematic reviews within the clinical risk paradigm, but a range of health literacy interventions that merit further review. Reviewing this literature is the focus of our study.

Existing reviews

There are numerous systematic reviews of health literacy interventions (e.g. Berkman et al 2011, Sheridan et al 2011, Visscher et al 2018) including for enhancing online health literacy (Car et al 2011, Jacobs et al 2016). These reviews tend to focus on interventions in the ‘public health paradigm’ of health literacy rather than the ‘clinical risk paradigm’ of interest in this project, although they sometimes include self-management interventions for chronic conditions that reduce emergency department visits (Sheridan et al 2011). A search of PROSPERO using the MESH term ‘health literacy’ revealed 92 reviews focused on the prevalence of limited health literacy, measurement of health literacy, association of health literacy with specific lifestyle behaviours or disease, effectiveness of interventions for self-management of specific chronic conditions, and interventions to improve medication adherence. There was only one review that might include interventions to reduce use of primary or emergency care: a review of health literacy interventions in low-middle income countries where the effect on emergency department visits was included in the list of outcomes. A Cochrane Library title-abstract search for ‘health literacy’ identified 12 reviews but only one was relevant; this concluded that there were not enough studies to identify effective interventions for enhancing online health literacy (Car et al 2011). A search of reviews in Google Scholar identified one relevant review of parental health literacy and paediatric emergency department use, where 7/8 studies showed that interventions reduced emergency department use (Morrison et al 2013). This review considered one specific patient group only.

There is an overlap between health literacy interventions and health information interventions. When looking for reviews we also used the term ‘health information’ (MESH term ‘consumer health information’) in PROSPERO and Cochrane and identified largely the same set of reviews.

Individual studies

Our simple searches of PROSPERO, and the Cochrane Library for individual studies of health literacy interventions to reduce primary and emergency care use identified a range of relevant studies. These included

- RCTs of leaflets to reduce GP attendance for minor ailments, either by the GP handing the leaflets out (Sustersic et al 2012) or by posting the leaflets to a general practice population (Little et al 2001),
- the use of educational text messaging to reduce emergency department use amongst parents (Ladley et al 2018),
- a paediatric emergency department-delivered information sheet and teaching session to reduce non-urgent help-seeking (Fieldston et al 2013),
- a community-delivered upper respiratory infection-related educational intervention on emergency department visits,
- mass media interventions on health care utilisation (Grilli et al 2002),
- a coaching intervention for people with limited health literacy to increase patient activation and thereby improve efficient use of emergency departments (Schumacher et al 2017).

Types of health literacy interventions

Health literacy interventions might include written information, educational workshops, health coaching, or digital interventions. Interventions might be delivered in different settings including within health services such as emergency or primary care, or outside health services in the community, schools or workplaces. They might be delivered at a patient, member of the public, patient group (e.g. parent of young children, asthma, carer), community or population level (in mass media campaigns). Patient Information Leaflets might focus on navigating the health care system or on managing illness (Protheroe et al 2015).

Interventions might be developed in different ways. For example, ‘Ophelia’ is an approach that develops health literacy interventions tailored to a specific community (Batterham et al 2014); it takes a systematic approach to identifying health literacy strengths and limitations of a community, co-creation of health literacy interventions, and implementation and evaluation of interventions using quality improvement cycles. The rationale is that this approach is more likely to develop effective interventions.

Policy initiatives on health literacy in the UK

National policy in England currently focuses on the 'public health' paradigm of improving health literacy. NHS England has set up a national collaborative consisting of three partners: Health Education England, NHS England and Public Health England. They have set up a demonstration health literacy site in the East Midlands to deliver 'Skilled for Health' which is a national evidence-based health literacy resource. The focus is on management of chronic conditions and health improvement, and on improving health literacy awareness amongst health practitioners, voluntary sector, and social services. Our proposal complements this national initiative. We will work with the NHS England Head of Health Literacy Jonathan Berry to ensure our work links with this national initiative (see later).

Focus of the review

It is important to consider

- how interventions were developed - health literacy experts believe that interventions may fare better if they are tailored to the needs of specific populations by getting the target population involved in development (Heijmans et al 2015).
- the range of types of interventions
- the content of interventions - some patient information leaflets may not promote health literacy because they are aimed at higher skilled patients (Protheroe et al 2015).
- the effectiveness and cost-effectiveness of any interventions -whether they reduce use of primary or emergency services and do so without being too expensive.
- safety – our PPI group expressed concerns about health literacy interventions potentially stopping people attending services with more serious problems.
- context - effectiveness may depend on the population sub-group being targeted (e.g. people with a chronic condition, elderly people, people with learning disabilities, parents of young children), the levels of health literacy within different countries, and the availability of contextual facilitators for delivery of interventions (e.g. national provision of community support).
- mechanisms of action - interventions may not work as planned. For example, one UK-based study to improve health literacy in the community through use of promoting self-care skills in the work place and toddler groups resulted in increases in hospital admissions and GP out of hours contacts but no change in emergency department use or overall health care use (cited in Heijmans et al 2015).
- Patient/carer and staff views on the feasibility, acceptability, appropriateness and meaningfulness of interventions

The review will also need to consider the relevance of the evidence base to the UK. Recommendations from the findings of the review can be reported according to the Joanna Briggs Institute FAME framework (Jordan et al 2019). This proposes consideration of the feasibility (e.g. is there sufficient levels of competency available), appropriateness (e.g. is it culturally acceptable) meaningfulness (e.g. is it not associated with negative experiences) and effectiveness and cost-effectiveness (e.g. is there a beneficial effect) of evidence to inform decision-making.

3a. Why this research is needed now

Demand is increasing at the same time as primary and emergency care face workforce challenges. Interventions that can safely prevent contact with GPs, ambulances and emergency departments for minor problems could help to take the pressure off these key services. We have found no relevant published, ongoing or registered systematic reviews but have found a number of relevant studies of health literacy interventions to reduce primary and emergency care use that could be synthesised in a systematic review. If we can find a set of interventions that have been shown to be effective or cost-effective and safe, and are relevant to the UK context, then we can work with national and local policy makers and services providers to identify localities willing to implement this evidence and evaluate its impact on service use in the real world.

4 RESEARCH QUESTION/AIM(S)

1. To identify the effectiveness, cost-effectiveness and safety of health literacy interventions that aim to reduce primary care or emergency services utilisation.

2. To construct a typology of health literacy interventions relevant to service use reduction that will include the range and content of interventions.

3. To identity the contexts in which different types of interventions are effective.

4. To identify mechanisms of action of effective interventions.

5. To describe effective and cost-effective interventions, including how they are developed, and literacy levels of information-based interventions.

6. To identify patient/carer and staff views on the feasibility, acceptability, appropriateness and meaningfulness of interventions.

7. To consider how our UK stakeholders could operationalise the evidence in terms of identifying a set of interventions they would find Feasible, Appropriate, Meaningful and Effective within their localities.

4.1 Objectives

1. To identify the effectiveness, cost-effectiveness and safety of health literacy interventions that aim to reduce primary care or emergency services utilisation.
2. To construct a typology of health literacy interventions relevant to service use reduction that will include the range and content of interventions.
3. To identity the contexts in which different types of interventions are effective.
4. To identify mechanisms of action of effective interventions.
5. To describe effective and cost-effective interventions, including how they are developed, and literacy levels of information-based interventions.
6. To identify patient/carer and staff views on the feasibility, acceptability, appropriateness and meaningfulness of interventions.
7. To consider how our UK stakeholders could operationalise the evidence in terms of identifying a set of interventions they would find Feasible, Appropriate, Meaningful and Effective within their localities.

4.2 Outcome

Changes in use of GP, GP Out of hours, ambulance, emergency departments, paediatric emergency departments (using a range of international terms for these services) overall or for minor health problems. Rate of adverse events, that is, missed serious health problems for which people would have otherwise sought care. Patient acceptability and health care feasibility and acceptability.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

A sequential study will be undertaken consisting of a Stakeholder Event to inform the systematic review, a Systematic Review to identify the evidence, and a Stakeholder Event to consider how to implement the evidence.

Stakeholder Event 1

At the start of the study we will hold a virtual Stakeholder Event involving patients and public, Clinical Commissioning Groups (CCGs), NHS England Emergency and Urgent Care representatives, the NHS England Health Literacy lead Jonathan Berry, and representatives of general practice, emergency departments and ambulance services. The intention will be to elicit stakeholders' perceptions of key issues that might further shape the review e.g. they may offer guidance on key types of interventions to include. The event will be undertaken in Month 1. We will hold a virtual event because of Covid-19. We will seek to ensure that PPI colleagues are fully included in this virtual event.

Systematic Review

This review will be a multi-component review (Gough et al 2012) of quantitative and qualitative research. We will undertake systematic, transparent and reproducible literature searches and use standard approaches to screening, data extraction and quality assessment of the included evidence. We have registered the review on PROSPERO CRD42020214206.

Searches

Database literature searches will be undertaken in the following: Ovid MEDLINE, the Cochrane Library (via Wiley Interscience), EMBASE (via OVID), CINAHL via EBSCO, PsycINFO (via OVID), Web of Science, Sociological Abstracts. We will also search for evidence in other sources including Google and web based review databases, such as Epistemonikos, PROSPERO and the Joanna Briggs Institute database. We will undertake a structured grey literature search which will be reported alongside our standard database searches. As this review is a multi-component review, searching will be iterative – following our initial searches, there will be supplementary searches to ensure we meet the aims and objectives of the review.

Search terms

The search will be developed by a professional, experienced Information Specialist within the Information Resources team in ScHARR. The search will be focused on the intervention elements of the standard PICO search approach.

Inclusion criteria: English language, 1990-2020, experimental, quasi-experimental, and non-experimental designs.
Population: All.
Intervention: Interventions with the primary purpose of reducing primary and emergency service use for minor health problems by improving health literacy. 'Minor health problems' will not be used to limit the initial search because researchers may not use this term (or similar terms), and may not articulate explicitly a focus on minor health problems. Instead we will

search widely and then screen for interventions to reduce help seeking for minor problems. Interventions are likely to focus on trying to reduce use of general practice for problems that could be dealt with at a pharmacy or through self-care, ambulance services for ambulatory conditions, and emergency departments for non-urgent conditions. There is an overlap between a 'public health' focus on health literacy and our 'clinical risk' focus; interventions to improve health literacy for those with chronic conditions will often have outcomes to reduce use of emergency care, including hospitalisation. These interventions tend to focus on self-management to prevent serious exacerbations, hence the interest in hospitalisation. We will not include these interventions in our review but accept that our broader search may identify this evidence.

Comparator: We intend to include a range of study designs, not only RCTs. The comparator will be usual care when we include RCTs.

Outcomes: Changes in use of GP, GP Out of hours, ambulance, emergency departments, paediatric emergency departments (using a range of international terms for these services) overall or for minor health problems. Rate of adverse events, that is, missed serious health problems for which people would have otherwise sought care. Patient acceptability and health care feasibility and acceptability.

Setting/context: We are interested in interventions that might work in the UK context. We will search for evidence without limiting the country/setting, then in the screening process will tag included references according to their geographical setting and within the review, then pay attention to transferability of evidence to the UK context. We will include interventions that operate in a range of settings including within health services, within the community, and at a national level.

Screening

First, two reviewers (LP and the Reviewer) will independently screen all the titles and abstracts (where available) retrieved from the searches to determine whether a study meets the pre-defined inclusion criteria. Each article will be tagged as 'include,' 'exclude' or 'unclear'. The full texts of all articles classified as 'include' or 'unclear' will then be retrieved for full review by the research team. An audit trail of the search and screening process will be kept and included in the final report.

Constructing a typology/taxonomy

There will be different approaches to/models of improving health literacy. There is no existing framework of models that we know about, so prior to data extraction we will read a selection of papers and inductively construct a framework for use during data extraction. This may be based on mechanisms of action, or the settings in which the intervention is used, or both. This framework will evolve during data extraction as we understand more about the range of interventions tested. We have used this approach successfully in other reviews (O'Cathain et al 2013, O'Cathain et al 2019).

Data extraction

Two reviewers (LP and the Reviewer) will independently extract each included study using a standard form (tested by the research team) that outlines the predetermined items for extraction. The data to be extracted will include: country of primary author; country where the research was conducted; category within framework; study design; service; context; target group; delivery setting; intervention type; basic outcome data; and headline message.

In addition, for the individual components of this multi-component review, bespoke data will be collected:

- Effectiveness, cost-effectiveness component: Data on the outcomes, costs, and safety of interventions. We will document whether general practice focused interventions have also measured any effect on emergency departments, to ensure we consider displacement of service contacts to higher acuity services.

- Contexts component: Although this review is not a realist review, we are interested in characteristics of context that contribute to reduction in use of primary and emergency services so our extraction form will also include data on this. Contexts will include country, health care system, and specific population sub-groups e.g. people who do not have English as their first language, people with learning difficulties, people from some ethnic groups, people who are unable to read, homeless people.
- Mechanisms component: We will identify mechanisms of interventions. For example, three potential mechanisms are 1. *Informing* people about services available at a suitable reading age, thus improving ability to identify and choose from the range of available services i.e. navigating the health care system. Leaflets and websites would address this mechanism. 2. *Educating* people about how to manage a health problem so they can undertake self-care, or how to navigate the health care system. This may include the use of leaflets, texts, and websites to help people to understand what actions to take to self-care, or reduce anxiety levels which in turn reduce the perceived need for contacting a health service or the perceived urgency of the problem. would address this mechanism. 3. *Empowering* people to communicate with health professionals or have confidence in their decision-making abilities by increasing patient activation, resulting in reduced anxiety etc. Educational workshops or health coaching would address this mechanism.
- Description and development of intervention component: Descriptions of interventions will be mapped against the TIDieR framework (Hoffman et al 2014) to articulate intervention components. Approaches to development of the intervention will be described.
- Qualitative component: Patient/carer and staff views on the feasibility, acceptability, appropriateness and meaningfulness of interventions.

Risk of bias (quality) assessment

Given the wide variety of study types that potentially will be included in this review, we will use a hybrid approach to risk of bias assessments. For RCTs we will use the Cochrane Risk of Bias tool. For non-randomised studies we will use the Newcastle Ottawa tool (case control and cohort studies). For any other experimental and non-experimental study designs we will use the relevant CASP checklist. Our assessment of risk of bias will not be used to exclude evidence from the review, but to assess the overall evidence base and the confidence with which we can use the evidence.

Strategy for data synthesis

- Systematic review of effectiveness and quantitative results on acceptability– data will be synthesised narratively and where possible meta analysed. For studies where interventions and outcomes are reported in terms of quantitative outcome measures, we will report these narratively, including effect sizes. Where the evidence permits, and there is sufficient homogeneity between the interventions and outcomes, we will perform a summative assessment of the evidence using meta analytic methods (Petticrew et al 2013). We will follow methods detailed in the Cochrane Handbook.
- Cost-effectiveness- It is unlikely that there will be many economic evaluations for synthesis. We will follow the ‘brief economic commentary’ rather than the ‘integrated full systematic review of economic evidence’ as set out in the Cochrane Handbook. This does not require health economic expertise. If it is possible, we will follow methods used by Angus et al 2014 where we will summarise any directly reported costs associated with interventions as reported in the literature and convert them to UK currency for a specific year. Where possible we will aggregate this data across intervention types in order to report costs for comparison. We will also, where the data permits, narratively synthesise cost-effectiveness and report the relationship between cost-effectiveness and context.

- Contexts and mechanisms component – we will identify context characteristics and mechanisms separately, and also consider their relationship by identifying context-mechanism-outcome chains associated with understanding messy complex interventions (Shaw et al 2018).
- Analysis of intervention content – an analysis of the components of interventions will be undertaken. We will describe interventions using the TIDieR framework. We will construct a typology/taxonomy of interventions as described earlier. We will assess information components of interventions using resources such as the NHS digital service manual for writing good information. https://beta.nhs.uk/service-manual/content/health-literacy and the Health Education England toolkit that aims to help people access, understand, appraise, and use information in order to understand the reading age and accessibility of these components.
- Qualitative component – the views of those who the intervention is targeted at, and those who deliver interventions, will be analysed using qualitative synthesis methods. These data will be extracted into evidence tables. We will analyse these using qualitative thematic analysis and synthesis methods (Harden and Thomas, 2008). We will consider the usefulness of integrating this qualitative evidence with the findings relating to effectiveness, cost-effectiveness and intervention content (Noyes et al 2019).

Stakeholder Event 2

Towards the end of the review we will hold a Stakeholder Event involving patients and public, Clinical Commissioning Groups (CCGs), NHS England Emergency and Urgent Care representatives, the NHS England Health Literacy lead Jonathan Berry, and representatives of general practice, emergency departments and ambulance services. Researchers and PPI representatives will co-present the evidence and work with the stakeholders to identify a set of interventions they would find Feasible, Appropriate, Meaningful and Effective within their localities. The event will be undertaken towards the end of the project (Month 10). It will not be held right at the end because stakeholders may identify issues for clarification, and we may need to return to our review to address questions arising about the evidence base.

We will start the event by describing the typology/taxonomy of different types of interventions identified in the review, promoting discussion on the feasibility, acceptability and meaningfulness of different types of interventions. Then we will present the review findings on the interventions with high quality evidence of effectiveness and cost-effectiveness, asking the attendees to discuss in detail how feasible the interventions might be for delivery within their locality and how acceptable they might be to people with low health literacy in their locality. We would hope to identify interventions that could be implemented within England, and identify uncertainties that might need to be addressed prior to implementation. Then we will move on to discuss interventions with a poorer evidence base which were identified as attractive from the typology discussions earlier in the day, discussing how best to generate future evidence.

6 STUDY SETTING

We are interested in interventions that might work in the UK context. We will search for evidence without limiting the country/setting, then in the screening process will tag included references according to their geographical setting and within the review, then pay attention to transferability of evidence to the UK context. We will include interventions that operate in a range of settings including within health services, within the community, and at a national level.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

First, two reviewers (LP and the Reviewer) will independently screen all the titles and abstracts (where available) retrieved from the searches to determine whether a study meets the pre-defined inclusion criteria. Each article will be tagged as ‘include,’ ‘exclude’ or ‘unclear’. The full texts of all articles classified as ‘include’ or ‘unclear’ will then be retrieved for full review by the research team. An audit trail of the search and screening process will be kept and included in the final report.

7.1.1 Inclusion criteria

English language, 1990-2020, experimental, quasi-experimental, and non-experimental designs.

7.1.2 Exclusion criteria NA

7.2 Sampling NA

7.2.1 Size of sample NA

7.2.2 Sampling technique NA

7.3 Recruitment NA

7.3.1 Sample identification NA
7.3.2 Consent NA

8 ETHICAL AND REGULATORY CONSIDERATIONS

Ethics approval is not required because it is a systematic review. The Stakeholder Events are not research; data will not be gathered.

8.1 Assessment and management of risk

None. It is a systematic review.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

NA

8.3 Peer review

The NIHR HS&DR panel and reviewers independently reviewed the project.

8.4 Patient & Public Involvement

Margaret Ogden (a member of the Sheffield Evidence Synthesis Centre PPI group – currently under restructure) is a co-applicant and will be part of the project management team, which will meet every two months, inputting into ongoing decision-making throughout the study. The Evidence Synthesis Centre PPI group in ScHARR is under restructure. We will use records of previous participants and our contacts to put together a project specific group with diverse members. We will work with the PPI group on the following occasions:

- In the early Stakeholder Event
- Near the beginning of the project when we are finalising the protocol for the review. The PPI group will help with ensuring our Plain English definition of health literacy is appropriate for all our needs, focusing the review after an initial search strategy has been applied, and prioritising the types of interventions to include (if necessary).
- When we have preliminary findings, so they can help to guide any further searching or synthesis.
- At the Stakeholder Event at month 10 to consider with other stakeholders how best to implement the evidence we have identified. We would support one of the PPI members to give a presentation at the Stakeholder Event so that a public/patient perspective is heard.
- At the end of the study to devise a dissemination strategy, including a Plain English summary that explains the findings of the review. They will help to identify the best way of communicating findings with diverse groups within the population, including those without computers. For example we have links with a number of local community workers and may want to disseminate findings through their local and national networks to reach a range of audiences.
- In between meetings. We will keep them up to date with progress on the project in between meetings.

After all meetings we will offer the PPI group feedback about how their contributions were acted on.

We will also take our early findings to the Yorkshire and Humber Deep End Public and Patient Involvement Panel. This is a panel of 10-15 people living in the most socio-economically deprived areas in Sheffield, established by a local GP. This will help us to think about aspects of the review specifically relevant to socio-economically deprived communities. We will also invite them to the later Stakeholder Event and expect a maximum of five to attend.

8.5 Protocol compliance

If we make any significant changes to the protocol we will seek permission from NIHR, who are funding the project.

8.6 Data protection and patient confidentiality

NA

8.7 Indemnity

NA

8.8 Access to the final study dataset

The included papers will be referenced and summarised in the final report and papers.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

We will publish an NIHR HS&DR report and an open access peer-reviewed journal article so others can use this work.

We will present the review at one national conference (Health Services Research UK in July 2022)

PPI will consider how best to inform the general population about the findings of the review. We have asked for funding to help PPI members to do this.

We will ask our stakeholders at our Stakeholder Event how best to inform different parts of the NHS. Primary care leads and urgent care leads in CCGs will be important stakeholders for dissemination. We will keep the NHS England Health Literacy Lead Jonathan Berry up to date with our emerging findings, invite him to our Stakeholder Event, discuss dissemination strategies with him to reach key NHS agencies, and see how we can link with current national health literacy initiatives. Jonathan Berry has agreed to work with us in this way.

9.2 Authorship eligibility guidelines and any intended use of professional writers

All co-applicants will be authors of the final report and any papers.

10 REFERENCES

Angus C, Latimer N, Preston L, Li J and Purshouse R (2014) What are the implications for policy makers? A systematic review of the cost-effectiveness of screening and brief interventions for alcohol misuse in primary care. Front. Psychiatry 5:114.

Batterham RW, Buchbinder R, Beauchamp A et al. The OPtimising HEalth LIterAcy (Ophelia) process: study protocol for using health literacy profiling and community engagement to create and implement health reform. BMC Public Health 2014, 14:694.

Berens EM, Vogt D, Ganahl K et al. Health Literacy and Health Service Use in Germany. Health Lit Res Pract. 2018;2(2):e115–e122.

Berkman ND, Sheridan SL, Donahue KE et al. Low health literacy and health outcomes: an updated systematic review. Ann Intern Med. 2011 Jul 19;155(2):97-107.

Car J, Lang B, Colledge A, Ung C, Majeed A. Interventions for enhancing consumers' online health literacy. Cochrane Database Syst Rev. 2011;2011(6):CD007092.

Fieldston E, Nadel FM; Alpern ER et al. Effects of an Education and Training Intervention on Caregiver Knowledge of Nonurgent Pediatric Complaints and on Child Health Services Utilization. Pediatric Emergency Care 2013;29 (3): 331–336.

Gough D, Thomas J, Oliver S. Clarifying differences between review designs and methods. Syst Rev 1, 28 (2012) doi:10.1186/2046-4053-1-28.

Griffey RT, Kennedy SK, D'Agostino McGowan L et al. Is low health literacy associated with increased emergency department utilization and recidivism? Acad Emerg Med. 2015 Apr;22(4):497.

Grilli R, Ramsay C, Minozzi S. Mass media interventions: effects on health services utilisation. Cochrane Database of Systematic Reviews 2002, Issue 1. Art. No.: CD000389. DOI: 10.1002/14651858.CD000389.

Heijmans M, Uiters E, Rose T et al. Study on sound evidence for a better understanding of health literacy in the European Union. Final Report. RfS Chafea/2014/health/01. European Commission. Brussels: June 2015.

Hoffmann TC, Glasziou PP, Boutron I et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ 2014;348:g1687.

Jacobs RJ, Lou JQ, Ownby RL et al. A systematic review of eHealth interventions to improve health literacy. Health Informatics Journal 2016;22:81-98.

Jansen T, Rademakers J, Waverijn G et al. The role of health literacy in explaining the association between educational attainment and the use of out-of-hours primary care services in chronically ill people: a survey study. BMC Health Serv Res 2018;18:394.

Jordan Z, Lockwood C, Munn Z et al. The updated Joanna Briggs Institute Model of Evidence-Based Healthcare. International Journal of Evidence-Based Healthcare 2019; 17 (1):58–71.

Ladley A, Waltos Hieger A, Arthur J et al. Educational Text Messages Decreased Emergency Department Utilization Among Infant Caregivers: A Randomized Trial. Academic Pediatrics 2018; 18(6): 636-641.

Little P, Somerville J, Williamson I et al. Randomised controlled trial of self management leaflets and booklets for minor illness provided by post. BMJ 2001;322:1214.

May M, Brousseau DC, Nelson DA et al. Why Parents Seek Care for Acute Illness in the Clinic or the ED: The Role of Health Literacy. Acad Pediatr 2018;18(3):289-296.

Morrison AK, Schapira MM, Gorelick MH et al. Low caregiver health literacy is associated with higher pediatric emergency department use and nonurgent visits. Acad Pediatr. 2014;14(3):309–314.

Morrison AK, Myrvik MP, Brousseau DC et al. Relationship Between Parent Health Literacy and Pediatric Emergency Department Utilization: A Systematic Review. Academic Pediatrics 2013;13 (5): 421-429.

NHS England (a). https://www.england.nhs.uk/five-year-forward-view/next-steps-on-the-nhs-five-year-forward-view/urgent-and-emergency-care/ (accessed 29/12/19).

NHS England (b). https://www.england.nhs.uk/ourwork/patient-participation/health-decisions/ (accessed 29/12/19).

Noyes, J., Booth, A., Cargo, M., Flemming, K., Harden, A., Harris, J., Garside, R., Hannes, K., Pantoja, T. and Thomas, J. (2020). Qualitative evidence. In Cochrane Handbook for Systematic Reviews of Interventions (eds J.P. Higgins, J. Thomas, J. Chandler, M. Cumpston, T. Li, M.J. Page and V.A. Welch). doi:10.1002/9781119536604.ch21

Nutbeam D. Defining and measuring health literacy: what can we learn from literacy studies? Int J Public Health 2009;54:303–5.

O'Cathain A, Knowles EL, Long J et al. Drivers of 'clinically unnecessary' demand for emergency and urgent care: the DEUCE mixed-methods study. Health Serv Deliv Res 2020;8(15).

O'Cathain A, Thomas KJ, Drabble SJ, Rudolph A, Hewison J. What can qualitative research do for randomised controlled trials? A systematic mapping review. BMJ Open 2013;3:e002889

O'Cathain A, Croot L, Sworn K, Duncan E, Rousseau N, Turner K, Yardley L, Hoddinott P. Taxonomy of approaches to developing interventions to improve health: a systematic methods overview. Pilot and Feasibility Studies 2019 5:41

Osborne RH, Batterham R, Elsworth GR et al. The grounded theory, psychometric development and initial validation of the Health Literacy Questionnaire (HLQ). BMC Public Health. 2013;13:658.

Petticrew M, Rehfuess E, Noyes J, et al. Synthesizing evidence on complex interventions: how meta-analytical, qualitative, and mixed-method approaches can contribute. J Clin Epidemiol. 2013;66(11):1230-1243. doi:10.1016/j.jclinepi.2013.06.005

Protheroe J, Estacio EV, Saidy-Khan S. Information materials in general practices and promotion of health literacy: an observational study of their effectiveness. British Journal of General Practice 2015; 65 (632): e192-e197.

Royal College of General Practitioners (a). https://www.rcgp.org.uk/about-us/news/2019/may/urgent-investment-needed-to-alleviate-intense-resource-and-workforce-pressure-on-gp-out-of-hours.aspx (accessed 29/12/19).

Royal College of General Practitioners (b). https://www.rcgp.org.uk/about-us/news/2019/january/new-data-analysis-by-the-royal-college-of-gps-has-found-a-concerning-decrease.aspx (accessed 29/12/19)

Schumacher JR, Hall AG, Davis TC et al. Potentially preventable use of emergency services: the role of low health literacy. Med Care 2013;51(8):654–658.

Schumacher JR, Lutz BJ, Hall AG, et al. Feasibility of an ED-to-Home Intervention to Engage Patients: a Mixed-Methods Investigation Western journal of emergency medicine 2017; 18(4):743-751.

Shaw J, Gray C, Baker GR, et al. Mechanisms, contexts and points of contention: operationalizing realist-informed research for complex health interventions. BMC Med Res Methodol. 2018;18(1):178.

Sheridan SL, Halpern DJ, Viera AJ et al. Interventions for Individuals with Low Health Literacy: A Systematic Review, Journal of Health Communication 2011; 16(sup3):30-54.

Sustersic M, Jeannet E, Cozon-Rein L. et al. Impact of Information Leaflets on Behavior of Patients with Gastroenteritis or Tonsillitis: A Cluster Randomized Trial in French Primary Care. J GEN

INTERN MED 2013;28: 25–31.

Thomas, J., Harden, A. Methods for the thematic synthesis of qualitative research in systematic reviews. BMC Med Res Methodol 8, 45 (2008). https://doi.org/10.1186/1471-2288-8-45

Ueki S, Komai K, Ohashi K et al. Parental factors predicting unnecessary ambulance use for their child with acute illness: A cross-sectional study. J Adv Nurs. 2019 Jul 26. doi: 10.1111/jan.14161. [Epub ahead of print]

van der Heide I, Heijmans M, Schuit J et al. Functional, interactive and critical health literacy: Varyingrelationships with control over care and number of GP visits. Patient Education and Counseling 2015;98:998–1004.

Visscher, B.B., Steunenberg, B., Heijmans, M. et al. Evidence on the effectiveness of health literacy interventions in the EU: a systematic review. BMC Public Health 2018;18:1414.

11. APPENDICIES

11.1 Appendix 1- Required documentation

NA

11.2 Appendix 2 – Schedule of Procedures (Example)

NA

13.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made