

BMJ Open Understanding how primary care practitioners can be supported to recognise, screen and initially diagnose oropharyngeal dysphagia: protocol for a behavioural science realist review

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ABSTRACT

Introduction Oropharyngeal dysphagia (OD) affects around 15% of older people; however, it is often unrecognised and underdiagnosed until patients are hospitalised. Screening is an important process which aims to facilitate proactive assessment, diagnosis and management of health conditions. Healthcare systems do not routinely screen for OD in older people, and healthcare professionals (HCPs) are largely unaware of the need to screen. This realist review aims to identify relevant literature and develop programme theories to understand what works, for whom, under what circumstances and how, to facilitate primary care HCPs to recognise, screen and initially diagnose OD.

Methods and analysis We will follow five steps for undertaking a realist review: (1) clarify the scope, (2) literature search, (3) appraise and extract data, (4) evidence synthesis and (5) evaluation. Initial programme theories (PTs) will be constructed after the preliminary literature search, informed by the Theoretical Domains Framework and with input from a stakeholder group. We will search Medline, Google Scholar, PubMed, EMBASE, CINAHL, AMED, Scopus and PsycINFO databases. We will obtain additional evidence through grey literature, snowball sampling, lateral searching and consulting the stakeholder group. Literature will be screened, evaluated and synthesised in Covidence. Evidence will be assessed for quality by evaluating its relevance and rigour. Data will be extracted and synthesised according to their relation to IPTs. We will follow the Realist and Meta-narrative Evidence Syntheses: Evolving Standards quality and publication standards to report study results.

Ethics and dissemination Formal ethical approval is not required for this review. We will disseminate this research through publication in a peer-reviewed journal, written pieces targeted to diverse groups of HCPs on selected online platforms and public engagement events.

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INTRODUCTION

The primary function of the swallow is to ensure safe transit of food, drink and medicine through coordinated movements in the mouth and neck, enabling nutritional and

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Realist methodology accounts for different contexts and outcomes, permitting us to garner learning from comparative literature on recognising, screening and initially diagnosing across all populations with oropharyngeal dysphagia (OD) as well as other health conditions to understand the mechanisms by which OD interventions may achieve their outcome(s).
- ⇒ Combining realist methodology and behavioural science to synthesise data in a review enables these mechanisms to be conceptualised as theoretical behavioural constructs, which is crucial to developing new complex interventions.
- ⇒ Through its linkage to a taxonomy of behaviour change techniques, using the theoretical domains framework as the theoretical basis to establish mechanisms of behaviour change permits identification of corresponding intervention components.
- ⇒ Only literature published in English will be included, potentially limiting the diversity of health systems captured in the review and the level of richness and relevance of evidence available in the included literature.

medicinal intake.^{1 2} Therefore, the process of swallowing is essential to sustaining life and maintaining a quality of life. Oropharyngeal dysphagia (OD) is a swallowing disorder which leads to difficulties safely manipulating and transporting a bolus from the oral cavity to the oesophagus.^{3 4} It is recognised as a geriatric syndrome and studies report a mean prevalence of 15% in the older population aged 60 years and older living in the community.^{3 5–8} However, OD is underdiagnosed and is likely to be higher than clinically reported as it is often overlooked by healthcare practitioners (HCPs).^{9–11} In their 2016 systematic review, Madhavan *et al* calculated that when applying this mean prevalence to the older population living in the community in

America, 2 million may be living with undiagnosed swallowing difficulties.⁵

Healthcare systems have a reactive approach to diagnosing and managing OD, with hospitalisation being the trigger to initiate the process.¹² Without the correct care, OD can lead to serious adverse outcomes including aspiration pneumonia, malnutrition and dehydration, with associated effects on patients' mental health.^{13–16} This can lead to avoidable hospitalisations, longer hospital stays and mortality.¹⁷ The reactive management of OD also impacts on the wider health system, with unnecessary health resource use and associated costs.^{3 17}

With an ageing population, the prevalence of OD is set to increase; thus, the importance of early diagnosis and management is even more pertinent to support people to age well.¹⁸ Screening is an important process which facilitates proactive assessment, diagnosis and management of health conditions to minimise risk and prevent harm.^{3 19–21} It is the first step in the dysphagia pathway and can be carried out by any HCP, in any setting, to ensure appropriate referral on to dysphagia specialists.²² For high-risk clinical groups, such as stroke survivors and people with Parkinson's, guidelines influence HCP behaviour to ensure early screening and assessment of dysphagia are undertaken.^{23–25} The aforementioned guidelines have led to an increase in OD screening behaviour in HCPs and reduced adverse outcomes for these patients.^{25 26} For other chronic conditions seen in the general older population, for example, dementia, the push towards early, routine screening in primary care has shown definitive improvements to identification and formal diagnosis rates.^{27 28}

Despite its prevalence and risk, findings from a 2019 cross-sectional study report that globally, most health systems do not systematically screen for OD in older people.^{6 29} Furthermore, a Canadian survey of HCPs reported that over half of respondents were not aware of the risks of OD and the need to screen for this in the general older population.³⁰ These factors are further confounded by a lack of systematic or routine processes and resources to support HCPs to proactively, rather than reactively, identify OD in the general older population, such as appropriate training or a recognised, validated screening tool.^{29–32} The existing reactive approach to OD management is further confounded by the lack of self-recognition of OD and low healthcare-seeking behaviour by older people.^{33 34}

While developing interventions to target patient behaviour is one potential strategy to address underdiagnosis of OD, patient-focused interventions can increase health inequalities, for example, if the patient does not have the required knowledge and skills to engage with the intervention.^{35 36} Conversely, HCP-focused interventions have not been linked to generating these inequities because HCPs can tailor the care they deliver as a result of the intervention to the needs of individual patients.^{37–39}

The Medical Research Council defines complex interventions to be those with numerous interacting

components which enable implementation, uptake and impact in real-world clinical practice.^{40 41} In order to address the numerous behavioural and contextual factors that are inhibiting HCPs to prevent harm from OD in the general older population, the development of a complex healthcare intervention is required.⁴⁰

As a new way of working, primary care HCPs will require support to work with patients to prevent harm from OD.^{42 43} Implementing new practices ultimately depends on changes in behaviour within the target context.⁴⁴ The importance of applying theory to understand the processes of behaviour change is widely recognised.⁴⁰ The theoretical domains framework (TDF) is a synthesis of behaviour change theories and provides a lens through which to understand the barriers and enablers to a new behaviour.⁴⁴ It also provides a framework from which to draw on strategies to address barriers and enablers to facilitate the desired change in behaviour.^{44 45}

Some barriers and enablers to preventing harm from OD in high-risk clinical groups may be relevant to the general older population and primary care context and thus some learning may be garnered from existing OD research. However, there are likely to be others that are context specific.⁴⁶ There is a wide body of evidence affirming the importance of context to behaviour change; therefore, while interventions designed to facilitate OD screening and initial diagnosis in other settings may provide useful learning, they are unlikely to be transferable to the primary care setting without refinement.⁴⁴

While there are several systematic reviews on available screening tools/processes to aid OD identification that focus on evaluating intervention efficacy,^{47–51} no realist review has yet been conducted to understand how interventions may work to support HCPs in identifying OD, and potentially implementing such screening tools. A realist review is a theory-driven variation to the traditional systematic review, which synthesises learning from existing literature, including grey literature.^{52 53} It aims to understand, analyse and explain the underlying mechanisms by which an intervention works or does not work, and takes into consideration the outcomes generated in varying contexts.^{52 54} During the realist review process, reviewers will identify the contextual factors that are hypothesised to have generated the relevant behavioural mechanism(s) to produce the positive or negative outcome(s). Most research on recognising, screening and initially diagnosing OD is based in hospitals; however, this review will pivot the focus of the research field towards primary care, better aligning with practice and policy, including guidance from the World Health Organisation on realigning primary care for an ageing population,⁵⁵ and patient expectations to focus on the delivery of healthcare in the community.

This review will apply a newly emerging approach, using behaviour change theory to conduct an evidence synthesis using realist methodology to understand what works, for whom, under what circumstances and how, to facilitate primary care HCPs to prevent harm from OD

in the general older population. It will develop initial programme theories (IPTs) using the TDF, a synthesis of behaviour change theories, and combine learning from existing OD screening interventions as well as from comparative interventions.⁴⁴ Through this approach, we will establish the causal behavioural mechanisms via which interventions relevant to preventing harm from OD are facilitating HCPs to identify and support people with OD and how context influences these outcomes. The learning from this review will underpin the development of a complex intervention to facilitate primary care HCPs in preventing harm from OD.

AIMS, OBJECTIVES AND RESEARCH QUESTIONS

Aim

- ▶ Synthesise learning from published and grey literature and develop programme theories to understand what works, for whom, under what circumstances and how, to facilitate primary HCPs to recognise, screen and initially diagnose OD.

Objectives

- ▶ Identify literature relevant to recognising, screening and initially diagnosing OD.
- ▶ Develop and refine programme theories, using the available literature and stakeholders, which outline the mechanisms of action through which OD identification and initial diagnosis may, or may not, work in the primary care setting.

Research questions

Preliminary research questions were developed using the experience and expertise of the core research team; this includes a realist methodologist (DB), behavioural scientist (SS) and an academic speech and language therapist (CS). These were then presented to the project's stakeholder group of patients, carers and HCPs for discussion and refinement using their relevant real-world and clinical experience to bring a diverse perspective on the research area. The following research questions were developed:

1. What are the determinants (barriers and enablers) of HCPs recognising, screening and making an initial diagnosis of OD?
2. What are the key HCP behaviours for recognising, screening and initially diagnosing OD?
3. What are the intended and unintended outcomes for patients, informal and formal carers, service providers or the wider healthcare system of interventions to facilitate HCPs to recognise, screen and initially diagnose OD?
4. What are the behavioural mechanisms by which interventions to facilitate HCP recognition, screening and initial diagnosis of OD result in their outcomes?
5. What are the contexts that influence the behavioural mechanisms by which interventions facilitate HCP recognition, screening and initial diagnosis of OD?

Due to the iterative nature of the realist methodology, these questions may be further refined to ensure the focus of the review is responsive to any new learning.⁵²

METHODS AND ANALYSIS

This realist review is registered on the international database of Prospectively Registered Systematic Reviews (PROSPERO; registration number: CRD42022320327). The review is scheduled to start in April 2022 and conclude in December 2022.

Realist review

A realist review is similar to the traditional systematic review in that it synthesises evidence using multiple sources.⁵² However, realist methodology is a theory-driven approach which aims to answer the question 'What works for whom under what circumstances, how and why?' rather than the traditional empirical research question 'Does this intervention work?'.⁵⁶ It addresses this aim by explaining the mechanism(s) by which an intervention works, or does not work, in certain contexts to produce the observed outcomes.⁵² Context is the background and setting surrounding an intervention that may play an integral part in its outcome(s). Examples of context from other realist work include: institutional settings, economic, political and organisational structures, circumstantial factors or cultural norms, which may trigger or inhibit the mechanisms within an intervention.^{57,58} There are varying definitions and interpretations of the term 'mechanism' across the realist community. This review will be underpinned by behaviour change theory and thus will report behavioural mechanisms defined as 'the process by which the active ingredients of an intervention affect behaviour'.⁵⁹ Outcomes are the intended or unintended, expected or unexpected outcomes from the intervention, as influenced by the interaction of the surrounding context(s) and underpinning behavioural mechanism(s).⁵⁸ Realism seeks to understand and represent these causal forces underpinning the success or failure of interventions.⁶⁰

Realist methodology centres around the creation and iterative development of programme theories. These hypothesise how and why an intervention may, or may not, work by exploring the theoretical relationships between contexts, which trigger particular behavioural mechanisms to produce certain outcomes. They are reported as Context, Mechanism, Outcome (CMO) configurations. Use of formal theory from disciplines such as behavioural science is an emerging approach, which provides a framework from which to generate and structure programme theories.⁶¹ Using the TDF, which is a synthesised framework of behaviour change theories, broadens the scope from which IPTs are generated and developed, and reduces bias arising from researchers' preconceived ideas.⁶² After IPT development, these will be tested against the synthesised literature included in the review to support, refine or refute their hypotheses.⁵²

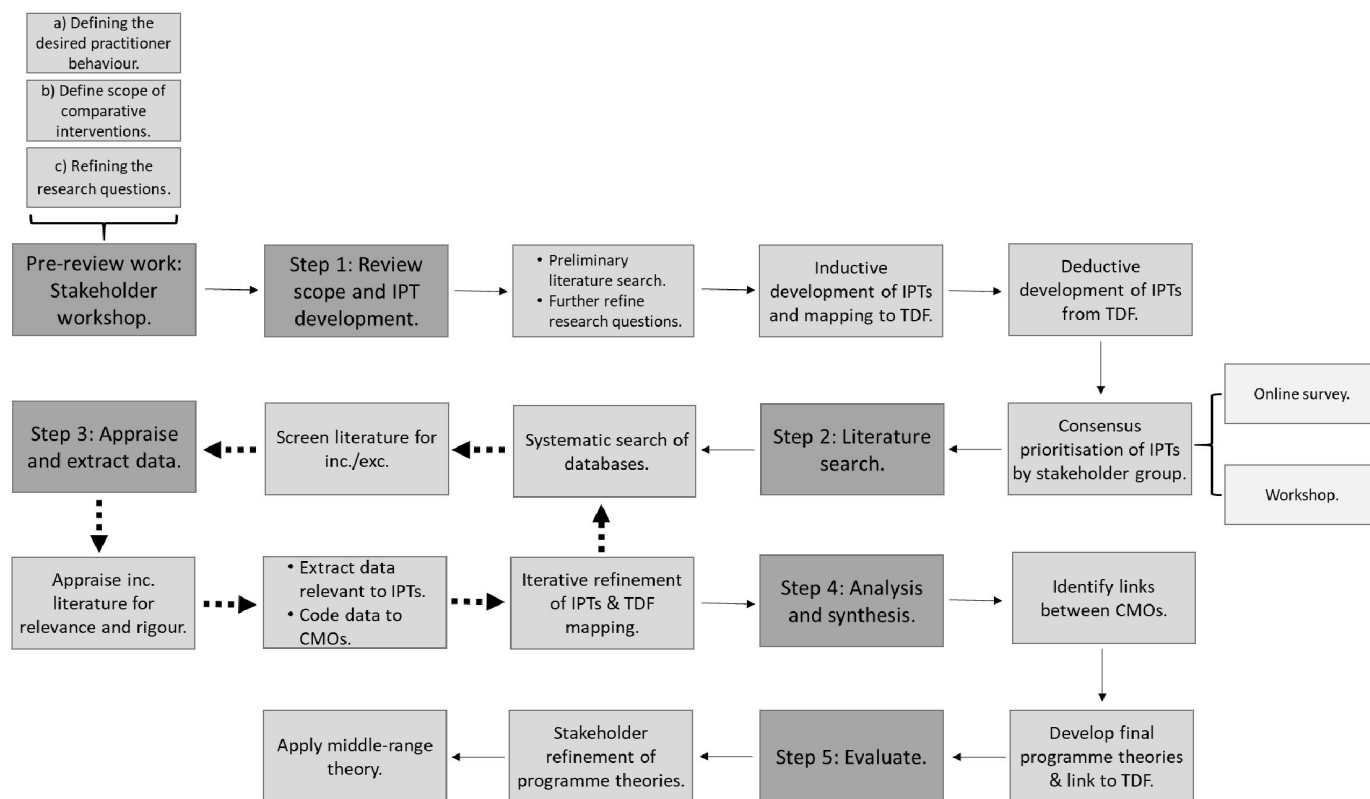


Figure 1 Overview of realist review design. CMOs, Context, Mechanism and Outcomes; IPTs, initial programme theories; TDF, theoretical domains framework.

Programme theories that are specific to the behaviour of interest are, therefore, not conducive to applying to other behaviours. Developing these programme theories into a middle-range theory facilitates application of the theoretical understanding to other behaviours.

This realist review will be conducted according to Pawson *et al's*⁵² five stages of conducting a realist review: (1) clarify the scope, (2) literature search, (3) appraise and extract data, (4) synthesise evidence and (5) evaluate. **Figure 1** details the steps that will be taken to conduct the review. We will adhere to the Realist and Meta-narrative Evidence Syntheses: Evolving Standards (RAMESES) quality and publication standards when reporting study results.^{60 63}

Patient and public involvement and the stakeholder group

To inform the design of this realist review, we have established a diverse group of stakeholders including: two patient and public involvement (PPI) advisors, comprised of a patient with lived experience of OD and a carer; two speech and language therapists; two geriatricians with primary care experience; a primary care pharmacist and a hospital pharmacist.

Prereview stakeholder workshop

A 2-hour workshop was convened in March 2022 with the stakeholder group to provide contextual expertise to underpin the development of this protocol. Workshop activities undertaken by the stakeholder group were:

1. Defining the specific HCP behaviour to target in an intervention to prevent harm from OD.
2. Defining the scope of comparative interventions to include in the review.
3. Refining the research questions that the review will address.

All decisions were based on collective agreement formed by the lived experience of our PPI advisors and clinical expertise of the HCPs. All members of the stakeholder group commented on the pertinence of the issues being addressed in the project. **Table 1** provides a summary of the themes of discussion across the three activities.

PPI advisors drew on previous experiences from other research projects as well as their own preferences as service users when considering what is needed to prevent harm from OD, especially as a condition that is not often reported by patients themselves. Healthcare practitioners drew on clinical experience to comment on the feasibility of proposed strategies to prevent harm in OD as well as highlighting areas of practice in comparative health groups to learn from. Important issues were raised by both HCPs and PPI advisors around the lack of awareness of OD and the importance of education in diagnosing health conditions. Input from the PPI advisors also considered burden to the patient in the process of recognising, screening and initially diagnosing OD and barriers to participation for populations with English as an additional language.

Table 1 Themes from stakeholder workshop activities

Activity 1: defining the specific practitioner behaviour	
Theme	Statements
Target population	Who do we mean by general older population?
	Frailty and vulnerability of adults not a universal experience once at a certain age. Some people may experience the effects of ageing earlier than others.
	Ambulatory patients living independently in primary care.
	Care homes a key population, but different approach required.
Awareness	More awareness needed of the condition itself.
	Education a priority to incite action.
Incentive	Cost prioritised over time in the health system.
	Introduce annual targets for swallow screening.
	HCPs need to be prompted by targets, pro formas and financial rewards to include screening for dysphagia in their health checks.
Practitioner role	Introduce dysphagia as a specialism in certain practitioner groups as seen in other health conditions, for example, Parkinson's nurses.
	To effectively pick up undiagnosed dysphagia, all HCPs must be able to recognise the symptoms of OD and conduct a simple swallow screen.
	Primary care role is about initial diagnosis and referral with secondary care and specialists providing management and treatment.
Acceptability to patient	Patients are happier to travel to their GP than outpatients at hospital.
	Including a swallow screen during other health check-ups/appointments.
	Patients welcome extra screening, initial diagnosis and appropriate, early advice before seeking specialist management and treatment.
	By incorporating screening into existing health check-ups/screens, it would be less intimidating and more practical.
Activity 2: defining the scope of comparative interventions	
Theme	Statements
Dementia and cancer patient groups	These patient groups cover a large diverse range of the population.
	Screening for dementia and cancer is prevalent in primary care.
	Targets and rewards incentivise early screening and diagnosis of these conditions.
	Large body of research to gather evidence.
Incentive	When screening activities are linked to targets, audits, Care Quality Commission, these act as an incentive and a trigger to increase screening and diagnosis.
Overwhelming the system	Long clerking pro forma to check for health conditions/concerns leads to HCPs feeling overwhelmed and elements missed.
	Need to make sure there is equity in who is screened—too costly to screen everyone and not enough resources to refer everyone who may potentially have OD.
	Target those at highest risk, but not currently covered groups for maximum effect and to establish trial sample size.
Self-administered screening	Patients receive screening tool by GP receptionist to fill in and handover to practitioner.
	Cognitive tests are an example of self-administered screening in the waiting room.
	Self-administered screening may exclude people who do not have English as their first language.
	Patients are more honest when talking directly to an HCP.
Activity 3: refining the research questions	
Theme	Statements
Recognising OD	Increasing awareness and education of OD in primary care HCPs.
Screening and initial diagnosis	Screening and making an initial diagnosis felt to be the key goal for primary care HCPs.
	Management and care may be more the remit of specialists and secondary care.
	Only the initial diagnosis to be given in primary care. A formal diagnosis will be given by the dysphagia specialists.

Continued

Table 1 Continued

Activity 3: refining the research questions	
Theme	Statements
Basic advice and adjustments	Providing basic advice and adjustments, for example, changing a medicine formulation, in primary care.
	May make the practitioner feel more empowered to carry out a screening test if basic advice can be provided afterwards.
	Any advice or adjustments given must be acceptable to the patient and within the remit of the HCPs' practice.
(Q3) Service provider	'Service provider' to replace 'organisations'. 'Organisations' did not relate to healthcare and the healthcare system.
GP, general practitioner; HCPs, healthcare practitioners; OD, oropharyngeal dysphagia.	

The existing literature on interventions to support HCPs recognise, screen and initially diagnose OD may be limited.⁶⁴ The research team in collaboration with the stakeholder group discussed other fields of healthcare research with comparative HCP behaviour from which the review could learn from. Workshop discussions predominantly focused on interventions which have been implemented to support primary care HCPs to recognise, screen and initially diagnose dementia and/or cancer. These were deemed to be suitable comparators by HCPs and PPI advisors due to: the broad population affected by the conditions (as seen in OD as well), existing screening and early diagnosis protocols in primary care and the richness of the research literature. Discussions also focused on feasible and practical delivery methods by which to recognise and screen for dysphagia in primary care. This included patient self-administered screening in general practitioner waiting rooms.

Following discussions on key HCP behaviours to prevent harm from OD, the wording of research questions, and throughout the paper, was changed from 'screening and management of OD' to 'recognising, screening and initially diagnosing OD'. Question 3 was further refined after discussions with the group. The term 'service provider' was agreed to replace the broader term 'organisations' to better outline the populations and settings that may be affected by the intended and unintended outcomes of the target interventions.

The group will continue to provide expertise during every stage of the review, including guiding the review scope, IPT development, data analysis, data interpretation and dissemination of the findings.

Step 1: clarify scope and develop IPTs

Review scope

A realist review starts with clarifying and refining the review scope and purpose.⁵² Development of the research questions forms a key part of this process. The five research questions were developed by the core research team and refined by the stakeholder group in the preliminary workshop. To ensure the review remains relevant to the problem being addressed, a preliminary literature search will be conducted to identify existing literature

on the influences to HCPs' recognising, screening and initial diagnosing OD and comparative conditions. We will search the following databases: Medline, Google Scholar, PubMed, EMBASE, CINAHL, AMED, Scopus and PsycINFO. Search terms will include terminology such as: Deglutition disorder; oropharyngeal dysphagia; dysphagia; screening; screening tool; initial diagnosis; primary care and; primary health care. Research questions will be iteratively refined in accordance with any emerging evidence in the literature with input from the stakeholder group where appropriate.

There are four approaches to conducting a realist review, as shown in table 2. This review will undertake a comparison approach when synthesising the literature to best understand 'What works for whom, under what circumstances, how and why?'.^{52 60} Adopting this approach will enable the review to identify how the same, or similar, interventions work or do not work across different contexts.⁵²

Development of IPTs

For this review, IPTs will be constructed after the preliminary literature search and with input from the stakeholder group. Rather than selecting any one formal theory to inform IPT development, we will use the TDF, which is a synthesis of behaviour change theories to identify barriers

Table 2 Realist review approaches

Review approach	Purpose
Theory integrity	Does the intervention work as predicted?
Theory adjudication	Which underlying theory of an intervention is most accurate in conceptualising how it works?
Comparison	How does the intervention work in different contexts, for different groups?
Reality testing	Does the intervention, as described and outlined in policy and by policymakers, translate into clinical practice?

and enablers of HCP behaviour change.^{44 62 65 66} The benefits of using this framework to guide IPT development include:

- ▶ Consideration and identification of a broad range of influences on HCP behaviour.
- ▶ Exploration of the influences of context at different levels, for example, individual, organisational and system.
- ▶ Providing a structured, but flexible, approach to the development of IPTs.

Once a list of IPTs has been generated by the core research team (CS, SS and DB), we will prioritise these using a modified nominal group technique approach. Nominal group technique is a consensus method used to reach solutions to research decisions through discussion, prioritisation and agreement.⁶⁷ IPTs will be prioritised through two phases: an online survey with the stakeholder group, followed by a workshop with the group to review and prioritise a manageable number of the most salient IPTs to test against the literature. This will ensure that the patients, carers and HCPs who have contextual insight relevant to recognising, screening and initially diagnosing OD will have identified what they perceive to be important about how these processes work.

IPTs with 100% rated as 'important' by all stakeholders in the online survey will automatically be selected for testing in the review. Those between 75% and 99% rated as 'important' will be discussed in the stakeholder workshop. Any with less than 75% agreement for 'important' will be excluded from any further discussion or testing.⁶⁸ If more than 25% rate as 'the meaning of this statement is unclear', then these will also be discussed in the workshop.

Step 2: literature search

Literature gathered and reviewed during a realist review is analysed and interpreted to 'confirm, refute or refine' all or components of programme theories.⁵⁶ As the realist methodology focuses on the underpinning causation of an intervention, evidence to prove or disprove IPTs will be sought from diverse types of literature, for example, grey literature, and bodies of literature, for example, allied health, pharmacy, etc.⁵² Grey literature includes sources of data that are not published in traditional academic journals, for example, guidelines, conference proceedings and blogs.⁴⁴ Realist reviews seek to include this type of evidence as they may provide richer information relating to the context, nature and evaluations of interventions.⁴⁵

In order to include all relevant literature to test and refine IPTs, we will search the following databases: Medline, Google Scholar, PubMed, EMBASE, CINAHL, AMED, Scopus and PsycINFO. The search will be conducted from inception. Search terms were developed within the core research team using the Medical Subject Headings thesaurus and assisted by a realist information specialist from the academic institution. A copy of the search strategies is provided in online supplemental file

1. We will identify further evidence for inclusion in the review by:

- ▶ Checking reference lists of studies identified in the literature search (snowballing).
- ▶ Citation searches, for example, using the 'cited by' filter on Scopus (lateral searching).
- ▶ Seeking input from the core research team and stakeholder group for other relevant publications.

Table 3 provides inclusion and exclusion criteria using the Population, Intervention, Comparator, Outcome format, a four-part model which facilitates a well-defined search strategy.⁶⁹ Evidence from all clinical populations who present with OD will be included in the review; however, as the literature on OD is likely to be sparse,⁶⁴ we will also include literature from comparative fields in health research. Preliminary discussions in the prereview stakeholder workshop specified these comparative fields. Unlike a traditional systematic review where the scope is defined a priori, the scope of the realist review develops as evidence is identified.⁵² The search strategy will, therefore, be responsive and iteratively developed as the review progresses, including purposive searching of evidence to support or refute the IPTs.

Systematic methods for searching and screening will follow the Preferred Reporting Items for Systematic Reviews and Meta-analysis guidelines.⁷⁰ Evidence found in the search will be imported into Covidence, an online program for managing evidence syntheses, including realist reviews.⁷¹⁻⁷⁵ Search results will initially be screened by title and abstract by two reviewers (CS and SS), progressing on to full text if eligible. A sample of title and abstracts will first be completed independently by the two reviewers and agreement rate calculated to determine the level of cohesion across the two reviewers before screening the remaining papers independently. Any remaining disagreements between the first two reviewers will be resolved through discussion with a third reviewer (DB) to ensure consistency in evidence inclusion. Further refinement of the review scope may be necessary depending on the number of evidence sources retained during initial screening. The core research team will implement new or revised inclusion/exclusion criteria if it is felt that additional studies may contribute to the refinement of IPTs.

Step 3: appraise and extract data

In the traditional process of a systematic review, appraisal of primary studies identified in the literature search ensures that flawed or low-quality studies are excluded. This principle is incorporated into realist methodology by adopting the RAMESES standards which merit the relevance and rigour of included literature.⁷⁶ Relevance is an evaluation of whether the content of the included evidence can contribute to the refinement of IPTs. Rigour determines whether the contents of the paper have sufficient substance to make credible contributions to the testing of IPTs.⁵²

We will then develop a data extraction form within Covidence, which will include fields relating to study

**Table 3** Inclusion and exclusion criteria

Inclusion criteria	
P—Population	HCPs, for example, doctors, nurses, pharmacists, allied health professionals. Patients or caregivers with real-world experience in services where HCPs recognise, screen and initially diagnose.
I—Intervention	Methods that implement interventions to recognise, screen and initially diagnose conditions.
C—Comparator	None.
O—Outcome	Outcomes of interest will depend on the nature of the intervention, but could include intended or unintended outcomes such as: HCPs, for example, knowledge/skills/behaviours needed to recognise, screen and initially diagnose the condition. Patients, for example, response to diagnosis of the condition, acceptance of advice/adjustments, relationship with HCPs. Process or implementation outcomes, for example, health service use, change in care delivery.
S—Setting	Any primary care or community-based health or social care service, for example, general practice, care homes, charities.
Study design	
No restriction on study design.	
Include non-empirical sources, for example, commentaries, guidelines, theses, etc through citation searches or identification through the core research team and stakeholder group.	
Exclusion criteria	
Non-English evidence.	
Evidence which focuses solely on interventions targeting patient behaviour.	
HCPs, healthcare practitioners.	

aims, design and methods, location, study participants, study outcomes, relevance to the initial and emerging programme theories and rigour. The form will be piloted on three sources of evidence collaboratively by two reviewers and then further refined. Once both reviewers are familiar with this process, data will be extracted independently by CS and SS and entered into the Covidence form. Sections of the relevant text from included evidence sources will be coded in Covidence originating from the data itself (inductively), or mapped to the relevant IPT(s) (deductively). All coded text will be labelled according to the relevant component of the CMO configuration it relates to. The two reviewers will meet on a weekly basis to discuss progress and resolve any queries prior to meetings with the rest of the research team to update on progress and make group decisions on the reviewer's work.

Step 4: analysis and synthesis

The assessment, annotation and organisation of the data may be undertaken simultaneously as the reviewers begin to understand and organise this information in relation to its role in refining programme theories.^{52 77}

Extracted data will be exported from Covidence into a Microsoft Excel spreadsheet to be synthesised according to their relationships within the CMO configurations of our IPTs.

The synthesis will comprise the following steps:

- ▶ Identifying themes across the codes amid emerging patterns among CMOs, to confirm, refute or refine IPTs.
- ▶ Linking the patterns to refine programme theories.

Throughout the evidence synthesis, the research team and stakeholder group will reflect on findings as they emerge to inform iterative development and refinement of programme theories. Retroductive reasoning will be applied to allow for refinements to initial and emerging programme theories through plausible inference of all available consolidated data.⁷⁸ We will question whether the programme theory is reliable and representative of clinical practices and experiences of HCPs and patients. Furthermore, we will examine and resolve competing theories and consider the implications of different contexts to the same theory. This will allow us to confirm, refute or refine the initial theory or even seek alternate or rival theories.

Step 5: evaluate

In order for the findings and recommendations of the review to be of relevance, considering the stakeholder perspective is essential.⁵² We will convene a final workshop and present back to the stakeholder group the prioritised IPTs and the proposed programme theories. Stakeholders will review the programme theories and refine as necessary.

The final output of the review will be a singular, middle-range theory, which will identify and explain the key contextual factors and behavioural mechanisms involved in the relevant processes to recognise, screen and initially diagnose OD in primary care.

ETHICS AND DISSEMINATION

This realist review will not involve any research participants external to the research at any point and thus

no ethical approval will be required. PPI advisors were invited to join the research team and are not research participants. We will disseminate this research through publication in a peer-reviewed journal as well as written pieces targeted to diverse groups of HCPs via selected online platforms. Our stakeholder group will also advise us on additional publications/sites to use when sharing review findings. Additionally, we will arrange a public engagement event to simultaneously share findings from this review and raise awareness of OD.

Following the conclusion of this review, we will apply for funding to co-design and then test an intervention to support primary care HCPs to recognise, screen and initially diagnose OD in older people.

Contributors All authors contributed to the protocol development. CS facilitated the stakeholder group workshop with SS and DB supporting. All authors reviewed and approved the final protocol manuscript. CS will carry out the review as part of a PhD with supervision from SS and DB.

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Competing interests CS and SS occasionally undertake consultancy for the pharmaceutical industry regarding the use of liquid medicines in oropharyngeal dysphagia.

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

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