

PROTOCOL

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Understanding shared decision-making among patients with limited health literacy: a realist review protocol

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Abstract

Background Over a quarter of adults in Europe have limited health literacy (LHL). LHL hampers their ability to find, understand, and implement medical information, resulting in poorer health outcomes. Shared decision-making (SDM), a process that enhances communication and personalised care and encourages patient involvement, can mitigate the challenges individuals with LHL face. However, healthcare providers often struggle to recognise and effectively engage these patients in SDM. This realist review aims to understand how, why, for whom, and under what circumstances SDM does or does not work for patients with LHL.

Methods Realist research provides a framework to understand how and why interventions work in specific contexts by uncovering underlying mechanisms. A realist approach is particularly suited for assessing complex social interventions like SDM. Our realist review, structured in three phases, focuses on developing and refining initial rough programme theories (IRPTs) in the form of context-mechanism-outcome configurations. Phase 1, now complete, involved defining the review scope and developing IRPTs enriched by the feedback of experts in realist-informed research methodologies. Phase 2 will include searching, selecting, and appraising the literature. In phase 3, we will focus on data extraction, analysis, and synthesis to further refine programme theories through stakeholder engagement, including patients with LHL and healthcare providers.

Discussion This realist review will provide valuable insights for optimising SDM interventions for patients with LHL, ultimately leading to greater inclusivity and engagement in healthcare and improved health outcomes for this vulnerable group. By elucidating the mechanisms at play, we can tailor these interventions to various contexts, enhancing their effectiveness and generalisability. This protocol presents not only the IRPTs but also provides a detailed description of the methods for the planned realist review. The results of the realist review will inform a subsequent randomised controlled trial and further refine programme theories through a realist evaluation.

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Keywords Realist review, Realist synthesis, Shared decision-making, Health literacy

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Introduction

At least 25% of adults in Europe have limited health literacy (LHL), with some countries experiencing levels as high as 75% [1]. Individuals with LHL often experience more struggles with navigating the health system, finding and understanding health information, managing their health by expressing their care needs, and preventing disease compared to more health-literate individuals [2–6]. Studies have shown that people with LHL are typically older, have lower educational levels and lower socio-economic status, live more frequently with chronic condition(s), and are often non-native speakers [7]. This group is more likely to experience poorer health outcomes due to delayed medical care, a higher risk of medication errors, and increased hospitalisation [6, 8]. While this population faces significant inequities and marginalisation [9], they stand to benefit significantly from engaging meaningfully during real-time healthcare service interactions. Shared decision-making (SDM) interventions have shown essential benefits for disadvantaged groups, including improved health outcomes, reduced disparities, and increased knowledge and participation [9].

SDM is a collaborative, person-centred approach that describes the process of making an evidence-based care plan for the patient supported by the healthcare provider [10, 11]. Although there is no standard process for SDM, the goal is to arrive at an evidence-informed decision tailored to the patient's needs and preferences. SDM hinges upon active listening and deliberation to foster an equitable relationship between patients and healthcare providers throughout decision-making. Healthcare providers frequently follow the comprehensive framework of Elwyn et al. [12], known as the three-talk model, comprising team talk, option talk, and decision talk to facilitate informed and collaborative choices [10, 12]. The team talk phase initiates collaboration, followed by the healthcare provider presenting all treatment options, including their evidence, risks, and benefits, to the patient during the option talk phase. This phase supports the patient in identifying their needs and preferences. Subsequently, in the decision talk phase, informed preferences are elicited, facilitating preference-based decisions and emphasising effective communication for informed decision-making. SDM can help patients with LHL articulate their health needs, express their experiences, and receive support in interpreting what these experiences mean for them. This collaborative approach enables them to reach a decision that better suits their situation.

Despite the potential benefits of tailored SDM interventions for patients with LHL, healthcare providers often need to be skilled to identify and effectively engage this patient population in the SDM process [13, 14].

Additionally, patients with LHL may feel less equipped, requiring more attention to understand care needs and their treatment plan, leading to a lack of assertiveness in the SDM process. Most traditional research methods only focus on measuring the effectiveness of SDM interventions. For instance, Durand et al. showed that the effectiveness of SDM interventions is highly dependent on patient characteristics, such as education level, socio-economic status, and health literacy [9]. Conversely, research efforts to understand how, why, for whom, and under what circumstances these interventions work or not for this vulnerable population remain limited [15]. More so, uncovering the underlying mechanisms that allow us to understand why this works differently for these groups has not yet been sufficiently described.

Realist inquiries are particularly suited for assessing complex social interventions like SDM initiatives [16]. Their methodological framework guides studies to understand how and why certain interventions work or do not work in specific contexts. Realist inquiries are based on the idea that interventions do not work the same way in every situation for every individual, and they try to uncover the underlying mechanisms that lead to outcomes by developing programme theories. The programme theories can help healthcare providers and policymakers tailor interventions to specific groups or contexts for patients with LHL in SDM to improve the intervention's chances of success and facilitate knowledge generalisation.

This realist review is part of a larger research project on SDM in the Netherlands [17] and will allow us to improve SDM for patients with LHL. The realist review aims to understand how, why, for whom, and under what circumstances SDM does or does not work in patients with LHL. This protocol details the development of initial rough programme theories (IRPTs) through a background literature search and expert engagement. The subsequent realist review will focus on refining these preliminary theories into more nuanced and precise programme theories. This protocol presents the IRPTs and provides a detailed description of the methods for the planned realist review.

Methods

A realist-informed understanding of how interventions work

Realist-informed approaches are particularly useful in evaluating complex and multi-faceted interventions like SDM. Realist-informed approaches are informed by realism, a philosophical approach proposing that reality exists independently of our beliefs or perceptions. Realism advocates for understanding the underlying structures and mechanisms that produce observable phenomena,

Table 1 Study example of context-mechanism-outcome configuration [22]

Term	Definition	A simplified example from this study
Context	Anything in the physical and social environment that is relevant to explaining why interventions are working for whom and under what circumstances	'Awareness of the importance of patient-centred care by healthcare providers'
Mechanism	What it is about the intervention that makes it work or not and how actors respond to this	'Healthcare providers are willing to improve their communication skills by means of training on SDM'
Outcome	The product of the interaction between the context and mechanism. The outcome can be intended or unintended, expected or unexpected	'Healthcare providers learn more about the patient as a person, leading to being better able to engage them in the SDM process'
Initial rough programme theory (IRPT)	How an intervention is expected to work. It describes the expected relationships between the intervention, the context in which it operates, the mechanisms it triggers, and the outcomes it aims to achieve (C + M = O)	'If there is awareness of the importance of patient-centred care by healthcare providers, then healthcare providers learn more about the patient as a person, leading to being better able to engage them in the SDM process, because healthcare providers are willing to improve their communication skills by means of training on SDM'
Rival theory	How the same intervention resources can trigger different responses by actors and lead to different outcomes. They challenge the assumptions and relationships proposed in the initial rough programme theory. These are valuable for improving the rigour of the intervention evaluation by considering multiple plausible explanations	'If there is little time to improve and apply the healthcare providers' communication skills, then this may lead to more absenteeism and professional burnout, because the healthcare provider is more aware of the needs and preferences of the patient on a deeper level, including difficult parts of their life making the healthcare provider overwhelmed'

those structures and mechanisms being ontologically different from the observed outcomes [18]. Adopting a realist perspective entails looking beyond surface-level observations to uncover the deeper, often hidden, generative mechanisms at work. Realist-informed approaches thus enable us to identify the causes of outcomes and their contextual conditions regardless of our assumptions about how or why they work [18]. Understanding the interplay between contexts and mechanisms can guide the targeting of interventions to similar contextual conditions or their adaptation to different ones [19]. Effective intervention implementation depends on matching and adapting them to various evolving circumstances [19].

The principle of emergence is central to understanding behaviour changes among individuals in realist-informed studies. The interplay between contexts and mechanisms in different ways, depending on other conditions and interactions, can form new outcomes, a phenomenon described as emergence. Emergence occurs when an event is co-determined by multiple interacting causal powers, but the emerging outcomes are not the sum of the parts. Emergence, therefore, underpins the explanations of how complex interventions like SDM produce new or different outcomes through the interaction of their components with different context conditions represented at different levels [18]. Therefore, realist researchers focus on uncovering the generative mechanisms and contextual factors that lead to these outcomes.

Emergence occurs because of the ‘complex’ nature of health systems. Interventions are implemented and operate within complex systems, where the same intervention can yield different results in different contexts [15, 18, 20]. This complexity necessitates a focus on how specific contexts influence people’s choices, leading to reoccurring patterns of behaviours called demi-regularities [20]. These demi-regularities usually align with regular habits, but they are not always predictable because different and unintended behaviours by the actor(s) could be observed in other contextual conditions [21].

By identifying underlying generative mechanisms and contextual conditions, we aim to understand from the available literature how, why, for whom, and under what circumstances an intervention does or does not work [20]. This can be done by developing context-mechanism-outcome configurations (CMOc) [16]. These configurations consist of the interaction between how contextual factors (C) trigger specific underlying mechanisms (M), which can lead to (un)intended and (un)expected outcomes (O) within the programme [22]. This CMOc can be extended by indicating the intervention (I) being implemented and the actors (A) involved in reacting to it.

Table 1 explains these configurations with a simplified example from this study. The context can be anything in

the dynamic physical and social environment relevant to explaining why interventions are working for whom and under what circumstances [19, 22]. Mechanisms are the underlying forces or entities that make an intervention work or not [22]. The outcomes are the product of the interaction between the context and mechanism, which can be intended or unintended, expected or unexpected [22].

Retroduction is an approach often used in realism to identify unseen generative mechanisms and refine them to explain how a phenomenon comes about [23, 24]. With retroduction, researchers first observe the phenomenon and then create hypotheses about the underlying causes or mechanisms that might explain the observed outcome. Realist researchers aim to understand *why* things happen, not just describe *what* happens. They will search for those underlying mechanisms and test and refine them further through data collection and analysis. This approach allows them to move beyond surface-level observations to uncover deeper realities that shape the observable world. Abductive reasoning can also help with this process, as it is a ‘hunch-driven’ way of thinking. Through abductive reasoning, researchers can creatively and intuitively conceptualise potential mechanisms for further investigation [24].

The IRPTs that follow the CMOc describe how the intervention is expected to work and explain the relationship between the context, mechanism, and outcome. When an IRPT shows how the same intervention resources can trigger different ways in which actors respond, leading to different outcomes, it is called a rival theory. Rival theories provide alternative explanations for how and why an intervention might (not) work. To ensure these IRPTs and rival theories are well-supported, researchers should appraise the available literature during a realist review, focusing on the three Rs: relevance, richness, and rigour. Relevance will help determine if the data from the literature has the potential to support the construction or testing of theories [16]. Appraising the literature on richness will ensure that sources capable of making meaningful contributions to the research question are included [25]. Assessing rigour will determine the credibility and reliability of the method utilised to produce the data from the literature [16]. When the IRPTs have been scrutinised against the available literature and proved (partly) wrong or (partly) right, they will be adjusted to form the refined programme theory (RPT). The RPT tries to come as close to reality as possible but may be further refined with upcoming available literature and knowledge. This iterative refinement process sets the stage for developing middle-range theories (MRTs), which occupy a middle ground between specificity and generality. MRTs are not focused on one specific

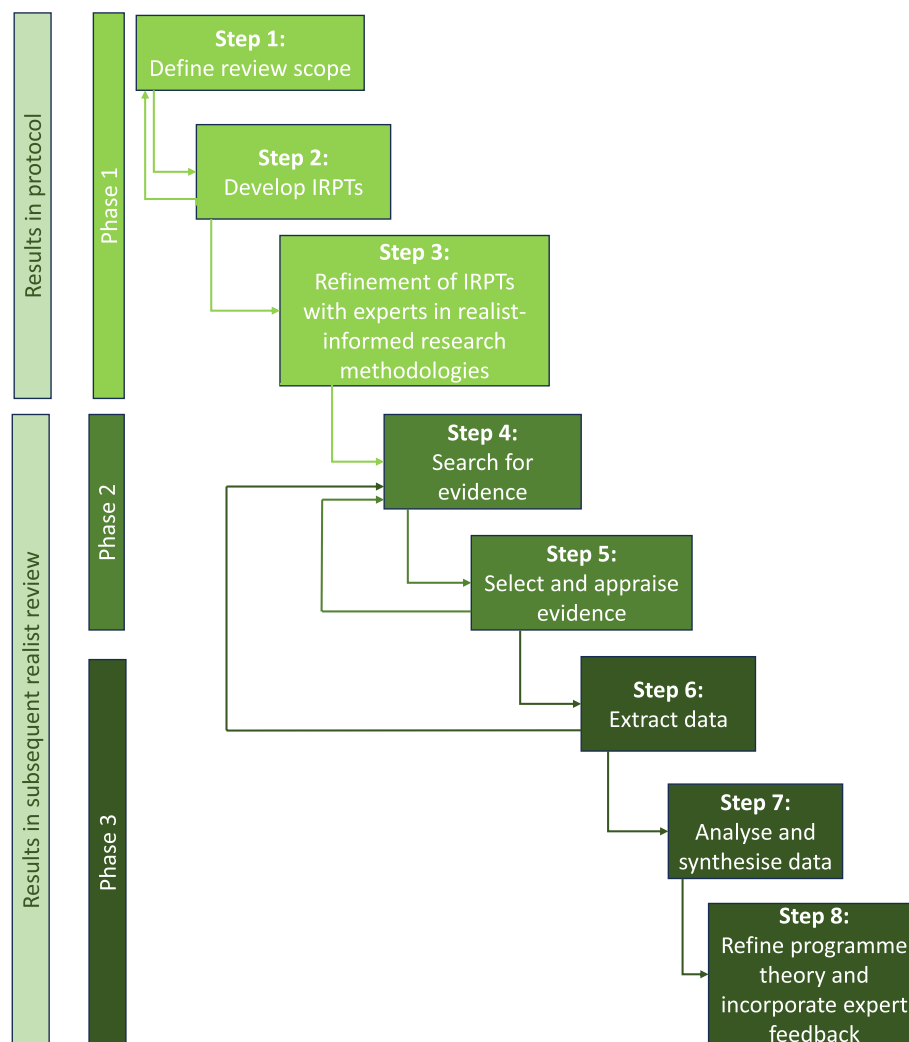


Fig. 1 Realist review steps present the iterative methods of this review process, which lead to the refinement of programme theories based on Dada et al. [26]

intervention, yet they are not overly abstract enough to fit all interventions. Instead, they offer a level of abstraction that allows for generalisability across similar interventions situated in different contexts [22]. MRTs are designed to be applicable across diverse settings, making them valuable tools for policymakers seeking to enhance the implementation of interventions in different contexts.

Structure of realist review

The structure of the realist review will follow the methodology adapted by Pawson et al. [15], the RAMESES publication standards [16], and the PRISMA-P guidelines (presented in Additional file 1), and builds on methodologies in recently published realist reviews and protocols [26–31].

Realist reviews inherently involve an iterative process that includes three phases, in which the CMOc are

constantly refined [15]. Figure 1 shows the three phases applied to this realist review. Phase 1 is the review preparation phase, which encompasses defining the review's scope and developing and refining the IRPTs. The results of this phase are presented in this protocol. In phases 2 and 3, the realist review is proposed: this will start with literature selection and appraisal (phase 2), followed by coding the data to form CMOc and iterative scrutinising and adapting of developed IRPTs to form RPTs (phase 3). The results of these phases will be presented in the actual realist review article. It is important to note that realist reviews do not adhere to the linear or strict protocol of a conventional systematic review. Realist reviews are intricate and inherently unpredictable, with decisions and adjustments occurring throughout the process rather than all criteria and specifications being predetermined [15].

Phase 1: review preparation

Step 1: define review scope

We started the preparation phase with a background search. For this purpose, we used databases such as PubMed and resources from organisations that provide information on SDM and health literacy in the Netherlands, such as the Netherlands Institute for Health Services Research (Nivel) and the Dutch Centre of Expertise on Health Disparities (Pharos) [32, 33]. The objective was to address the variations in definitions associated with health literacy and LHL and definitions associated with SDM, thereby gaining a deeper understanding of the topic and refining the focus of our research.

Health literacy There is a wide variety of definitions when it comes to health literacy. Conversations persist regarding whether health literacy should be viewed as an individual skill or a systemic one and whether it is static or dynamic [34]. This ongoing debate adds complexity to efforts to enhance LHL [34]. This complexity arises because different definitions and perspectives have led to varying approaches and strategies to improve LHL. However, the complex nature of health literacy itself also contributes to these different definitions and perspectives, leading to challenges in healthcare in implementing fitting interventions for people with LHL. Defining the concept of health literacy remains challenging because it is dynamic and can improve or worsen over time, and it depends on the environment [35]. For example, health literacy abilities can change over time due to different interactions with various healthcare providers. It also depends on the severity and complexity of the care needs the person is experiencing at that moment. In this paper, we used the frequently cited World Health Organization's (WHO) definition [36]. They define health literacy as 'the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health' [37]. Building on this definition, Nutbeam's model categorises health literacy into three levels [38]. Functional health literacy involves the essential reading and writing skills required in everyday activities. Interactive health literacy requires more advanced cognitive and literacy skills combined with social skills. This allows individuals to actively engage in everyday activities, gather information, interpret different communication forms, and adapt to changing situations. Finally, critical health literacy involves the most advanced cognitive and social skills, allowing individuals to critically evaluate information and use it to make informed decisions and gain greater control over their health, life events, and situations [38].

We believe an individual's health literacy abilities are not static nor exclusively individualistic; they fluctuate over time, influenced by changes in their experiences, skills, or the healthcare system [34]. As people improve their health literacy levels over time, they may also gain independence and feel more empowered, which could lead to better health outcomes, improved self-management, and more assertive involvement in SDM [38, 39]. Enhancing health literacy is not solely about transmitting health information more effectively; it also involves boosting patients' confidence in their ability to use this knowledge. This can be achieved through health education that engages patients as active participants rather than passive recipients. These efforts can be implemented at various levels, including population, community, and personal [38].

Shared decision-making SDM can be integrated into population health management (PHM). The WHO defines PHM as 'a people-centred, data-driven and proactive approach to manage the health and well-being of a defined population, considering the differences within that population and their social determinants of health. Population health management entails data-driven assessment of the health status of a specific population followed by prediction of health outcomes and anticipating the resources needed to proactively address these' [40]. Person-centred care has emerged as a PHM strategy and a cornerstone in healthcare in response to increasing calls for a shift from a paternalistic approach to a more inclusive approach [1–3]. SDM can be integrated into PHM as a person-centred intervention that aligns with the broader goal of achieving a more accessible, equitable, and efficient healthcare system. Our definition of SDM is a collaborative, person-centred approach that describes the process of making an evidence-based care plan by the patient supported by the healthcare provider following the three-talk model by Elwyn et al. [12]. The three-talk model is highly cited worldwide and is often familiar to healthcare providers, as we have observed during the small-scale implementation of our multi-stage SDM programme [12, 17]. By empowering individuals and fostering collaboration between patients and healthcare providers, SDM enhances the quality of care and can help support the population's overall health.

Our investigation initially centred on SDM, specifically within the context of patients with type 2 diabetes and LHL. Our research group focuses on exploring SDM practices among patients with type 2 diabetes. To this end, we have developed a multi-stage SDM programme based on existing literature and in collaboration with stakeholders. This programme is currently undergoing

small-scale implementation. A detailed description of this programme is provided elsewhere [17].

To ensure that the results of our realist review can be relevant to other health conditions, we expanded our scope to include a diverse range of chronic conditions rather than limiting our focus to SDM in type 2 diabetes. Differences in how SDM functions across conditions—for example between physical and mental health problems, which place different challenges on patients related to meaningful participation—are considered contextual factors within realism that may lead to SDM working differently. Broadening the scope of our review in this way enables more healthcare providers and policymakers to apply future findings to various chronic disease management situations. Ultimately, this will also improve person-centred care across different healthcare settings.

Step 2: develop initial rough programme theories

The development of IRPTs started with employing abductive reasoning to systematically document our pre-existing knowledge about causal insights into how, why, for whom, and under what circumstances SDM works or does not work in patients with LHL. We started the abductive reasoning with a set of initial thoughts and progressed towards the most plausible explanation for the given set through interpretation and re-contextualisation [18]. After starting with abductive reasoning, we needed to familiarise ourselves more with the existing body of work on SDM and LHL, so we searched the literature again. This led us to go from 15 to 30 IRPTs. To enhance the coherence of our IRPTs, we have opted to categorise them by looking at the different actors involved in SDM. We distinguished the IRPTs between the perspectives of the patient with LHL and the healthcare provider, recognising the importance of understanding both sides of the SDM process. Through deliberations within our research team, we narrowed our IRPTs to those most pertinent to testing the literature.

Retroduction was employed as a methodological approach to developing explanatory theories beyond mere observation and correlation, aiming to uncover the underlying causal mechanisms that produce observable phenomena [17, 18]. This approach resulted in ten IRPTs, including five rival theories.

The background literature search and final refinement of step 2 aimed to deepen our understanding of causal insights on how, why, for whom, and under what circumstances SDM does or does not work in patients with LHL. This helped address potential tensions or gaps in the literature. We concluded this step by rephrasing the IRPTs as CMOC using the ‘if...then...because’ statements

for improved readability. Consequently, we identified a set of nine IRPTs, including two rival theories.

Step 3: refinement of initial rough programme theories with experts in realist-informed research methodologies

With the aid of three realist experts, we refined and consolidated our nine IRPTs into six to elicit how, why, for whom, and under what circumstances SDM does or does not work among patients with LHL. These IRPTs were formulated by synthesising contextual factors, mechanisms, and outcome configurations identified in steps 2 and 3 of our methodology.

Visual representations of the IRPTs were developed to provide a comprehensive understanding of SDM processes from both the patient with LHL and the healthcare provider's perspectives. Figure 2 presents three IRPTs from the patient's perspective, while Fig. 3 illustrates three IRPTs from the healthcare provider's perspective.

Our development of IRPTs revealed four overarching contextual factors that appear to influence the implementation and outcomes of SDM in both perspectives. These include (1) culture of engaging in SDM; (2) transformational leadership and organisational culture; (3) patient-centred care delivery method; and (4) awareness of limited health literacy among patients.

From the patient perspective, presented in Fig. 2, we highlighted some key contextual factors besides the overarching contexts. Patients with LHL often lack awareness of SDM and are influenced by their prior experiences with SDM and therapeutic relationships with healthcare providers (C). Patient decision aids (I) or active encouragement by the healthcare provider (I) can activate or deactivate underlying mechanisms within these contexts. Positive alignment of these contextual factors can increase patient confidence, empowerment through knowledge acquisition, and perceived support (M), ultimately resulting in enhanced SDM participation and improved health outcomes for the patient with LHL (O).

In examining the healthcare provider perspective in Fig. 3, we identified several key contextual factors that influence the effectiveness of SDM besides the overarching contexts. Providers' time constraints during consultations and reluctance to deviate from established practices (C) may present barriers to effective SDM implementation (O). Conversely, heightened awareness of SDM principles and the strength of the provider-patient bond (C) serve as facilitating contexts for SDM engagement. Interventions, such as patient decision aids and healthcare provider education (I), play a role in activating mechanisms within this context. These mechanisms include increased confidence in SDM skills, heightened motivation to engage patients with LHL, and enhanced trust in the capabilities of this patient population (M). Positive

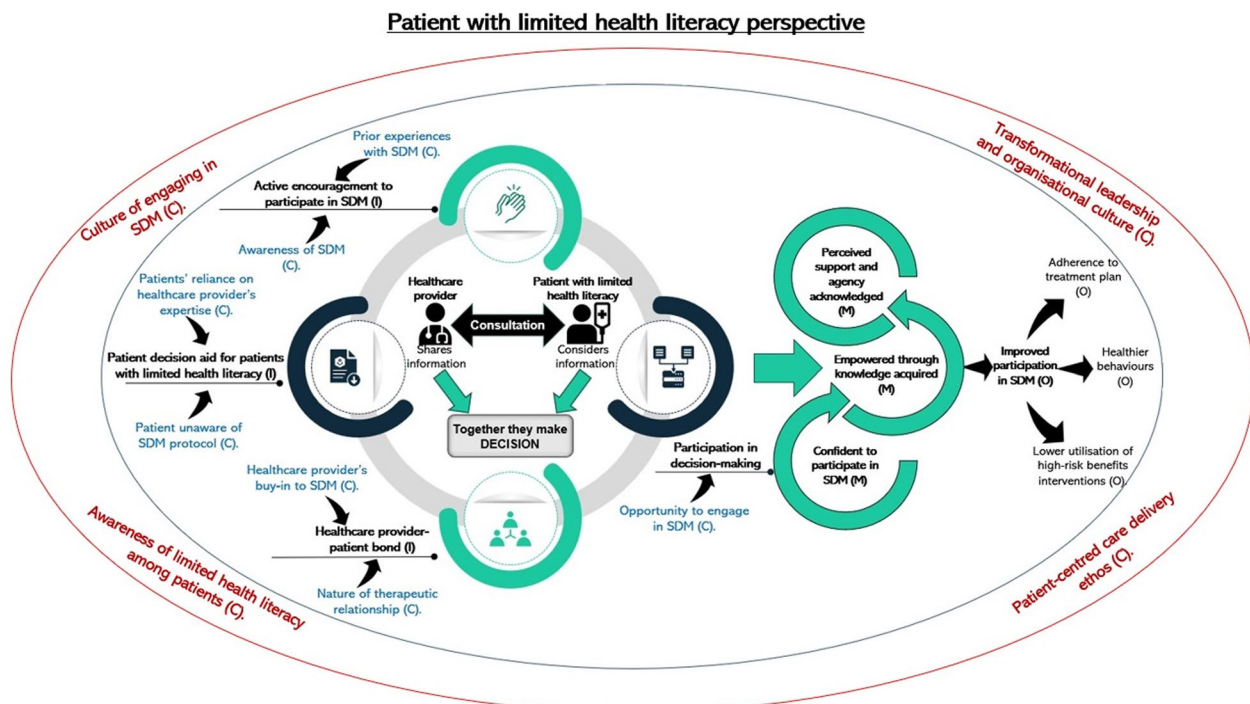


Fig. 2 Initial rough programme theories visualisation from the patient with LHL perspective

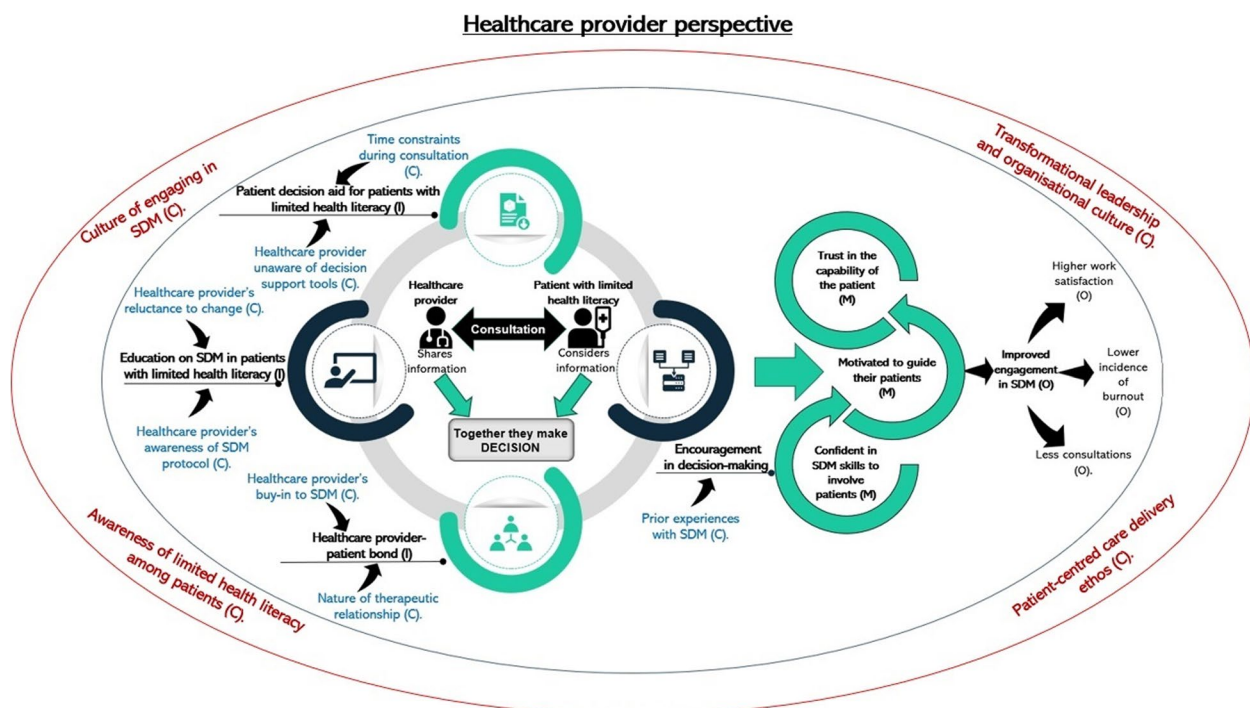


Fig. 3 Initial rough programme theories visualisation from the healthcare provider perspective

alignment of contextual factors leading to activating these underlying mechanisms can result in improved engagement in SDM (O). This, in turn, contributes to

higher provider work satisfaction, reduced incidence of professional burnout, and fewer consultations needed (O).

Phases 2 and 3 will elaborate on the methods used in the realist search, analysis, and synthesis. The results of these phases will be presented in a subsequent paper on the realist review.

Phase 2: literature selection and appraisal

Step 4: search for evidence

Phase 2 focuses on exploring the literature to find supporting evidence for testing the IRPTs from phase 1. Therefore, the realist search will employ a purposive selection of the literature to examine the IRPTs. Additionally, we will conduct iterative searches employing forward citation tracking to identify newly relevant papers. We will supplement this approach with snowballing by tracking citations from included references. This thorough process aims not only to explore supporting evidence but also to investigate any emerging hypotheses, acknowledging the iterative and ongoing nature of the review [15, 16].

For the realist search, academic databases PubMed, EMBASE, Web of Science, SCOPUS, and CINAHL [41] will be searched. This search will yield peer-reviewed academic papers, as well as grey literature, including preprints from EMBASE and conference proceedings from both EMBASE and SCOPUS. This process is guided by terms derived from key publications in health literacy and SDM [9, 13, 14, 42]. A librarian at Maastricht University will guide us in forming search terms and combinations of those, including ‘shared decision-making’, ‘decision-making’, and ‘health literacy’. Additional grey literature will be explored in Google and Overton [41]. This can provide a broader range of information, including reports from organisations like Nivel and Pharos and policy documents in English or Dutch. All searches will be conducted in English, except for the search for grey literature, which will also be performed in Dutch. The search terms and databases might change throughout the searches since, in a realist review, the search is iterative, and any changes to, among others, the search terms are possible [16]. These changes will be documented. The search results will be shown in a PRISMA-type flow diagram to ensure the transparency of the entire search process [41].

Step 5: select and appraise evidence

The realist search will yield a certain number of articles. Endnote 21.2 will be used to deduplicate studies. Further duplicates will be removed by hand, as reference software is not always reliable [43]. The decision to include or exclude articles will be based on relevance, defined as the article’s contribution to the building of the programme theory [16]. The WHO definition of health literacy served as a guiding framework for screening potential sources by

helping determine whether the study populations could be classified as LHL [36]. Rayyan, a web and mobile app designed for systematic reviews to organise and manage data, will create order when screening the remaining articles for relevance.

Two rounds of screening for relevance will be conducted, as described in Hunter et al. [28]; see Additional file 2 for the tool that will be used to screen the literature in this step. In the first screening round, the title and abstract will be screened by NdG, with papers scored on a five-point scale indicating their level of relevance. Reasons for exclusion will be noted, and 20% of all references will be cross-checked by another researcher from the research team (DH) for consistency. Papers categorised as ‘likely irrelevant’ will be excluded, and papers categorised as ‘less relevant’ will be set aside for further consideration, while the remaining articles will proceed to the second screening round. At the end of step 7, we will come back to the papers categorised as ‘less relevant’. We will consider their use depending on the theory development at that moment in time and the categorisation reason noted in Rayyan [44].

During the second screening round, full-text articles will be assessed with another tool combining relevance, richness, and rigour (3 Rs), as seen in the second part of Additional file 2. Richness assesses the extent of explanatory detail offered, and rigour is evaluated based on the trustworthiness of the data [44]. The assessment of these 3 Rs will adhere to the RAMESES publication standards [16] and follow the recommendations of Dada et al. [44]. This assessment will help form judgements regarding the potential contribution of each article to programme theory development. These judgements will be discussed and ranked by NdG, with input from the research team. No evidence will be excluded based solely on rigour, adhering to standard realist review practice [44]. Less rigorous data will be supplemented with additional or more credible data and otherwise be presented as having ‘less rigour’ [44]. All documents providing pertinent evidence will be incorporated into this review, whether to support the programme theory or the programme architecture. The extraction table will ensure transparency when presenting the 3 Rs appraisal process outcomes.

Phase 3: programme theory refinement

Step 6: extract data

To analyse the data from the assembled literature, we will use Atlas.ti 23. This software will enable us to highlight key information, take notes, and apply labels, facilitating the identification of causal insights describing how, why, for whom, and under what circumstances the intervention is supposed to work based on the developed IRPTs

from phase 1 [15]. This method of coded annotations is inspired by the work of Peters [45].

An extraction table based on Hunter et al. [28] will be filled in to capture the characteristics of the included literature. This table will document the type of study, appraisal scores, and the specific CMOc to which each piece of literature contributes (see Additional file 3).

Step 7: analyse and synthesise data

CMOc will be formed and added to the causal insight notes/labels from Atlas.ti 23 in Microsoft Excel. CMOc will be organised into thematic groups, facilitating a clearer line of reasoning for the reviewer and aiding in mapping the data [45]. The CMOc will be modified through refinement, refutation, or combination as needed during the synthesis process when emerging causal insights on the context, mechanism, or outcome come to light [45]. As mentioned in step 6, the source of each (part of the) CMOc will be noted in the extraction table for clarity. To ensure transparency, changes to the CMOc will be documented in a separate table. Consolidation may be necessary to handle large volumes of data through data reduction [45]. For example, in cases where multiple CMOc offer a hunch of similar explanations, they could be combined through abductive reasoning. We will ensure that the merged CMOc still reflect the data and will be clearly stated when it occurs.

These CMOc will be brought together in a conceptual map in Microsoft PowerPoint [15] and will display the interconnections between insights from different data sources, such as interviews from qualitative papers, pre-prints, and reports from health literacy organisations, to develop, refine, or refute the IRPTs. To contend with the risk of bias in realist reviews where researchers may seek evidence to fit their theory, the researchers will not only try to confirm but also falsify the IRPTs. This will be done similarly to the resulting IRPTs from phase 1.

The thematic groups and conceptual map will also assist in identifying recurring key concepts, facilitating the formulation of MRTs. These MRTs, derived from the main identified themes, support multiple parts of the programme theory by providing insights into the context, mechanism, and outcome [22].

Step 8: refine programme theory and incorporate experiential and professional stakeholder feedback

The programme theories and MRTs will be distributed in focus groups with multiple patients with LHL and healthcare providers operating in Dutch primary care. Patients with LHL and healthcare providers will be invited to actively participate in further refinement by providing input and suggesting modifications to the programme theories through a workshop or interactive seminar. This inclusive approach ensures that the perspectives and

insights of patients with LHL and healthcare providers are considered, enhancing the relevance and applicability of the resulting policies. The programme theories and MRTs will be translated into Dutch and simplified to include experiential and professional stakeholders successfully. Since translations can alter a given meaning or emphasis, a specialised translator will be asked to provide a second reading of these IRPTs.

Furthermore, we will re-engage with the three experts in realist-informed research methodologies to solicit advice on the programme theories and MRTs. After the refinement of the programme theories, with their feedback, we will alert the policy community with specific cautionary notes and aspects to consider when making decisions rather than presenting universal scientific truths [15]. As Pawson et al. [15] demonstrated, examples include advising policymakers to be 'aware of the importance of A' or to exercise 'caution regarding B'. This approach aims to find a linkage between research and policy by offering insights that inform decision-making without oversimplifying complex issues.

Discussion

Some may argue that a protocol for a realist review seems redundant, given the iterative nature of realist research, in contrast to the often strict nature of a protocol. However, a realist review protocol may be valuable because realism involves various aspects and approaches that must be clearly outlined. Informing readers about the specific realist lens used, the terms in the review, and the exact steps taken helps to ensure the transparency of the study and, thus, judgements about its quality and reliability. A protocol provides a comprehensive introduction to the topic, details the extensive methodology, and serves as a stepping stone for subsequent papers, allowing cross-referencing. Including IRPTs in the protocol prepares for the realist review and directs the search and data analysis when navigating the available literature.

Strengths and limitations of the realist approach

The realist approach is well-suited to exploring SDM in patients with LHL, as it focuses on understanding how and why interventions do or do not work in specific contexts. It allows for the identification of CMOc, which may provide more nuanced insights that can inform both policy and practice. The iterative nature of realist reviews enables the review focus to adapt as understanding deepens, thereby enhancing relevance.

However, realist approaches are also subject to limitations. The researcher's perspective influences the interpretation of the CMOc, which may introduce some subjectivity into the results. The comprehensibility of the realist approach also depends on the availability and

quality of existing literature. Additionally, realist assumptions require careful consideration and retroductive thinking, as causal pathways are often complex and not always directly observable.

In our review, these strengths allow us to integrate diverse chronic conditions and healthcare settings and account for variations in SDM processes. At the same time, we remain cautious about overgeneralising our findings, striving to obtain middle-range theories over grand theories. This process of generalising entails recognising that we are developing and refining a programme theory that offers a plausible explanation rather than absolute reality.

Next steps in our research

The refined programme theories emerging from our realist review will lay the groundwork for our future research. This includes designing and implementing a randomised controlled trial and realist evaluation, which will enable further refinement of our theories through real-world observations. Ultimately, our overarching goal is to deepen our understanding of SDM among patients with LHL, paving the way for more inclusive and equitable healthcare interventions tailored to this marginalised population and their healthcare providers.

Abbreviations

LHL	Limited health literacy
SDM	Shared decision-making
IRPT	Initial rough programme theory
CMOC	Context-mechanism-outcome configuration
C	Context
M	Mechanism
O	Outcome
RPT	Refined programme theory
MRT	Middle range theory
RAMESES	Realist and Meta-narrative Evidence Syntheses: Evolving Standards
WHO	World Health Organization
PHM	Population health management

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13643-025-03039-z>.

Additional file 1.
Additional file 2.
Additional file 3.

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Authors' contributions

This article was written as part of a PhD project by N. de Graef under the internal supervision of D. Hertroijs, D. Ruwaard, and A. Elissen and the external supervision of J.M. Cramm. Both F.C. Mukumbang and G. Westhorp acted as experts in informed realist research methodologies and co-authors. N. de Graef wrote the first draft of the manuscript, and all co-authors commented on all versions of the manuscript. All authors read and approved the final manuscript.

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Data availability

Data generated during this study are mostly included in this published article and its supplementary information files. Earlier versions of the IRPTs with background information and feedback from the experts in realist-informed research methodologies are not included in the published article but can be requested from the author.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

Nienke de Graef, Dorijn Hertroijs, Ferdinand C. Mukumbang, Gill Westhorp, Jane M. Cramm, Dirk Ruwaard, and Arianne Elissen have no conflicts of interest to report.

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