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DETECT – DEveloping and testing a model to identifying vision loss among older paTients in gEneral praCTice: Protocol for a complex intervention aiming at improving health care services and patient support in primary care

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Abstract

Introduction: The number of people living with visual impairment and loss is increasing due to sociodemographic changes resulting from an aging population. Visual impairments cause loss in quality of life and reduce self-care abilities. The burden of disease is heavy for people experiencing visual impairment and their relatives. The severity and progression of diseases such as glaucoma and age-related macular degeneration (AMD) are highly dependent on the time of detection and treatment options, making timely access to health-care critical in reducing visual impairment. General practice plays a key role in public health by managing preventive healthcare, diagnostics, and treatment of chronic conditions. General practitioners (GPs) coordinate services from other healthcare professionals. More involvement of the primary sector could potentially be valuable in detecting visual impairment.

Methods: Medical Research Council (MRC) framework for complex interventions to develop a primary care intervention with the GP as a key actor, aimed at identifying and coordinating care for patients with low vision. The development process will engage patients, relatives and relevant health-professional stakeholders. We will pilot test the feasibility of the intervention in a real-world general practice setting. The intervention model will be developed through a participatory approach using qualitative and creative methods such as graphic facilitation. We aim to explore the potentials and limitations of general practice in relation to visual impairment.

Ethics and dissemination: The study meets the requirements from the Helsinki declaration and will be disseminated through research papers and to the broader public through podcasts and patient organizations.

Strengths and limitations of this study

1. Visual impairment and vision loss are important health problems. But the role of general practice in relation to detection of visual impairment remains unclear. Through the Medical Research Council framework for complex interventions, this study seeks to unfold the potentials and limitations of the GP's role concerning visual impairment and vision loss

2. The study applies a participatory approach and explores the method of graphic facilitation to engage patients, relatives, GP's and other health professionals in the development of the intervention
3. The intervention will be tested in a real-world general practice setting, which will ensure relevance and long-term acceptability of the intervention model
4. Limitations include that the intervention is in the pilot phase and will need to be tested in a larger scale at a later stage before wider implementation can be initiated

Introduction

Worldwide the age-standardized rates of preventable blindness have decreased, but age-standardized rates of moderate to severe visual impairment have not (1). It is estimated that 2.2 billion people have impaired vision, and of these, at least 1 billion people have a vision loss that could have been prevented or reduced by earlier detection or by access to treatment (2). The most common causes of moderate to severe visual impairment are uncorrected refractive errors, un-operated cataract, age-related macular degeneration, glaucoma and diabetic retinopathy (1). Also in affluent welfare states, such as Denmark, visual impairment constitutes a problem. Insights from such health care systems may not be directly applicable in less affluent settings, but are likely to point at more general structures that can inform future studies.

The incidence of visual impairment increases with age, and due to the sociodemographic trajectory of an increasing elderly population, the prevalence of patients with visual impairment will increase (3). Timely access to health care has a major influence on the progression of eye conditions (1,2). The consequences of vision loss significantly affect the person's quality of life (4–6), dependence (7) and increases the risk of recurrent falls and fractures, which is a significant threat to mobility in old age (8–12). A YouGov poll showed sight was by far the sensory function people fears losing the most (13). Vision loss can result in worsened mental health (14,15), cognition (16,17) and social functioning (4). Disease progression can be complicated by other chronic conditions (18) and can complicate management of multimorbidity due to decreased self-care, ability to visit clinics and adherence to medication. Finally, vision loss can increase the risks of placement in nursing homes (19,20). Thus, visual impairment and loss has great impact on the individual, their relatives (21,22), society in general and on the healthcare system.

General practice and visual impairment

GPs handle preventive healthcare, diagnostics, treatment and care of chronic conditions as well as coordinate services from various healthcare professionals (23). In the Global North, the GPs handle the majority of all medical matters. A survey set in English general practice from 1998 concluded that eye problems, including undiagnosed glaucoma and age-related macular generation (AMD), were quite frequent among elderly patients consulting their GP (24). One study found that patients are more likely to have their eyes checked if their GP suggests it (25). Additionally, an increased focus on eye health in at-risk populations in general practice is suggested to be more effective for early detection than broader screening programs (26,27). However, a recent UK-based survey of GPs indicated that although up to five percent of the primary consultations were eye-related, GPs ability to identify red flags was low (28). The literature points to a gap where, even though patients are in contact with their GP concerning symptoms related to their vision, an unidentified number of patients may suffer from unrecognized visual impairment that is not detected in general practice.

Collaboration across healthcare professions

Since vision problems are rarely detected in general practice, the need for research into how patients and health professionals collaborate to identify and manage visual impairment becomes a relevant matter. This is in line with a recent Cochrane review, which concludes that future research should look at optimized primary care-based vision screening interventions (29). Patients with visual impairment often have contacts with many different healthcare professionals (30). It is therefore important to incorporate collaboration across health professions and sectors in a GP intervention aimed at improving identification of patients with visual impairment.
Optometrists constitute an occupational group who may be the first line of contact for some patients who experience visual changes. Optometrists will in most cases operate independently without a formal collaboration with other health professionals such as GPs (31). Given the optometrists contact with the patients and level of equipment for measuring vision and evaluating the eye, they pose a potentially important resource when collaboration across healthcare professions is rethought and are therefore important to include in the study. Their commercial agenda must be considered when collaborating (32,33) and their work must be validated.

Aim and objectives

In this study, we aim to develop a health intervention in a Danish general practice setting to improve the detection and care of visual impairment. The patient target group is middle-aged and older

adults and their relatives, with GP's constituting the primary professional target group. We define visual impairment broadly to be the patient experience of symptoms related to vision and symptoms identified by health professionals – such as reduced vision field – not yet experienced by the patient, but a serious threat to patient vision. Visual impairment is in this respect not connected to specific diagnoses, but as previously stated, we assume frequent eye-diseases such as glaucoma and AMD will be well represented.

The overall aim of DETECT is thus to:

1. Develop an intervention in general practice aimed at identifying visual impairment among elderly patients with chronic conditions.
2. Test the feasibility of the intervention model in general practice with a focus on ensuring improved patient support and education.

Methods and analysis

The study will be conducted in Denmark and is thus inscribed in a Scandinavian health system with universal access to health care. The general health status in Denmark is relatively high, and as far as vision is concerned, the incidence of legal blindness has decreased along with improved treatment options (34). The average life expectancy has increased over the last 70 years, which is positive, but it also entails a rise in age-related sight-threatening eye diseases such as glaucoma and AMD (35). Despite the decreasing incidence of legal blindness due to AMD, many patients are diagnosed late with irreversible vision loss. It seems relevant to diagnose eye diseases earlier and optimize the coordination of care. It is difficult to provide an exact number of people in Denmark who live with visual impairment. A national survey of health, quality of life and morbidity from 2007 shows that 3.8% of the population over 60 reported difficulties in reading a newspaper text (36), while the Danish Eye Association estimate that 50.000 people in Denmark above 60 years are blind or visually impaired (37) (total population 60+: 1.554.542 (38)).

In Denmark, the GP is the patient's primary entry point to the healthcare system, and the GP treats 90% of all medical cases (23). All Danes are assigned to a default general practice, and as many as 80% consult their GP at least annually, with an increased frequency among elderly patients aged 50 or older. People over 65 are offered an annual health check at their GP, and a Danish survey from 2019 showed that 82.4% of men and 86.7% of women had their vision measured at one of these consultations within the last three years (39). However, these figures are from 2010 to 2017. In 2017, regulations regarding driving licenses were changed, resulting in vision being measured only

every 15 years. This may result in a lower frequency of vision acuity measurements at the GP today, but from the 2017 figures we can assume that the practice of performing vision measurements during the annual consultation for older adults is a well-known procedure.

Ophthalmologists can diagnose, treat and carry out the necessary checks of e.g., glaucoma and dry AMD in the primary sector. If indicated, patients are referred to secondary care in the hospitals´ eye departments. Examples of referral indications may be wet AMD, proliferative diabetic retinopathy and progressive glaucoma. At the hospitals, ophthalmologists work publicly funded and university hospital clinics have an obligation to do research within the field.

Consultations with the GP or ophthalmologist are free of charge to the patient (40,41). Hospital-based eye clinics are also free, but the patient must be referred by a primary sector ophthalmologist for treatment. In cases of acute vision loss or pain, patients can be seen directly in the emergency room and referred from there to the on-call ophthalmologist in the hospital eye department. Anyone can book an appointment with the ophthalmologist in the primary sector without a referral, but due to a low number of ophthalmologists, it is often difficult to book a consultation within a reasonable time frame and geographical distance. On the other hand, the GP must be available to all patients inscribed in his/her practice, and have an in-depth knowledge of the patient's general health and condition. The GPs therefore seem to be in an ideal situation to identify visual impairment and coordinate the management.

It's estimated that around 2000 optometrists operate in Denmark (total population 5,8mill.) and opticians shops can be found in most smaller cities, making it accessible even in rural areas to visit an optician shop (42,43). In most optician shops, it is free of charge to have vision tested. Many optometrists offer intraocular pressure measurements and fundus photographs as additional procedures for a fee. Optometrists are thus a professional stakeholder that we find interesting to explore further.

Study phases

The study will apply an exploratory sequential method design by first producing qualitative-based data to develop a model aimed at identifying visual impairment in a primary care setting. The model will be tested in general practice for feasibility including a cohort study in general practice to validate the proof-of-concept.

Developing the intervention includes a variety of settings, stakeholders and policy concerns. We apply the Medical Research Council guidance on developing, testing and evaluating complex

interventions (44,45). As a result, we produce a programme theory as part of our theory-driven intervention, which will guide our feasibility test and evaluation process (46). To operationalize the framework for complex interventions, we apply a temporal structure from the tradition of human-centered design to divide the project cycle into the three main phases; (I) identifying the problem, (II) developing the model and (III) testing the feasibility of the model.(47) We are explicitly reflective on, how process and product are interwoven and to a very high extent dependent on the context it unfolds within (44,48).

The intervention explores what patients, carers and professionals perceive as pivotal to improve detection, navigating care and health services and support possibilities for people living with visual impairment, following a structured and well-documented design process to identify the changes made and insights produced.

[INSERT Figure 1[1]. *Figure 1: DETECT overall study design and participants engaged.*]

Phase I: Identify –Identifying key issues to address in the health intervention through a participatory process

The aim of Phase I is to explore the problem we are addressing. Visual impairment in the middle-aged and elderly population consists of a variety of diagnoses with cataract, glaucoma, AMD and diabetic retinopathy being among the most common (1). We are conducting background interviews with a broad selection of relevant stakeholders to help us map the current practice in detecting and diagnosing eye conditions and qualify our Phase I data production in phase I.

[INSERT figure 2. *Figure 2: Stakeholders identified to participate in a background interview*]

An essential element in human-centered design processes is to create understanding and empathy for the end-user (49,50) – in our case people living with visual impairment and their relatives. We aim to incorporate a wide spectrum of eye-diagnoses and develop a model to identify and diagnose visual impairment that works from the onset of the patient's early symptoms, such as stumbling over doorsteps, difficulties in reading, distorted vision or difficulties related to the transition from dark to light spaces and vice versa. The intervention aim of increased patient support also includes

[1] Figures were created with BioRender.com

support of relatives, who carries a large part of the burden of the disease and may experience stress and depression due to their loved one's visual impairment (51).

Patient and public involvement in Phase I

Patients, relatives and professionals will be involved by providing their perspectives in various stages of the study and co-design core elements of the model constituting the intervention. The patient engagement process is informed by a thorough report produced by the Danish Center for Social Science Research on older adults with visual impairment and vision loss (35). The report underlines the need for increased knowledge on how visual impairment affects patients' every-day life in all aspects. The experiences, needs, preferences, and values of patients and relatives will thus be explored (52). See Figure 1 for an overview of the involvement of participants across the three project phases.

In Phase I, we perform semi-structured interviews with patients and relatives, preferably in their homes to gain an insight in their experiences in the context in which they occur. Here we focus on the patient journey from the time patients experience symptoms leading to a diagnosis and handling life afterwards with a diagnosis. After the interview, patients and relatives are encouraged to contact the researcher if they would like her/him to participate in e.g., a visit to the ophthalmologist or if they have further input or concerns at a later stage.

We will furthermore perform focus-group interviews with older adults to investigate (1) the expectations to vision in old age and (2) which health professionals' older adults identify as relevant when they experience vision changes. The focus-group interviews supplement the interviews with patient and relative with a view to gaining insight into the social norms and prominent attitudes towards visual impairment among older adults. The participants in the focus-group interviews are asked to complete the validated Visual Function Questionnaire-25 to provide more individual knowledge about the participants own perception of their vision function (53).

Through participant observations, we will generate knowledge on the everyday working environment and challenges that health professionals, private optometrists and communal workers navigate in concerning people with visual impairment (54).

Phase II: Develop – Developing an intervention-model for improved detection and support of visual impairment in general practice

In Phase II, we will operationalize the insights from Phase I. This will be done through three consecutive content-developing workshops using the creative method of graphic facilitation (55). Graphic facilitation is well suited when elaborating on ideas and problem-solving processes (56,57). We invite a graphic facilitator to execute three workshops using wall-to-wall paper, where the inputs from the participants are captured and connected during the workshop. Choosing a visual method to engage participants could seem an unusual choice in a project focusing on visual impairment and vision loss. However, the participants are not blind. They live with a visual impairment, which poses a range of consequences and constraints in their every-day life, but it does not prevent them from being able to participate in a graphic facilitated workshop. If needed, relevant aids will be provided – in example to enlarge the graphic recordings on a tablet. The benefits of graphic facilitation includes a transparent process, open to multiple agendas. The method can be relevant for redistributing power and expertise in a co-design activity and the physical product of the three content workshops will act as design principles for the intervention. Project researchers will participate as observers in the three workshops.

The three workshops: Based on the results from phase I, the graphic facilitator and project researchers develop a template for the workshops. Participants for the workshops are recruited among participants in phase I.

Workshop 1:

In this workshop, the graphic facilitator engages 3-4 patients and 3-4 relatives to formulate a graphic recording on what is lacking in the identification, diagnosis and patient support concerning visual impairment.

Workshop 2:

The output of the first workshop will form the template for this workshop, where two GP's, two ophthalmologists and two optometrists will co-design possible solutions for the health services concerning visual impairment. Importantly, the health professionals are asked to identify key eye examinations and measures that would be feasible in a general practice setting as well as to identify the most relevant prevalent progressive severe eye diseases. Lastly, a proposal for an organizational structure for the collaboration between the health professionals are formulated.

Workshop 3:

At the last workshop, patients and relatives from the first workshop wrap up the work conducted by the health professionals and validate the graphic recordings from a patient's and relative's perspective.

The graphic recordings from the three workshops constitute a collective overview of core elements to include in the intervention-model. The project researchers will recapture the insights and design the model.

Phase III: Feasibility– Feasibility test in general practice

Part 1:

We will test the model in 2-3 general practices to establish face validity and adjust according to the experiences. The model must be clinically relevant and feasible for implementation in a clinical practice. Data production continues in this phase through observational studies and interviews with GPs to disseminate the experiences with the model in general practice and whether the model can be part of improved collaboration between health professionals.

Part 2:

Based on findings from part 1, we will expand the intervention by including ten to fifteen GP practices in the Capital and Zeeland Region, Denmark to participate in testing the GP's possibilities and barriers to detect visual impairment and vision loss. According to previous literature (36), we need to include 1500-2000 patients in general practice aged 65 or older to identify 150-200 with visual impairment. The practices will receive the developed intervention-model and recruit in up to 18 months. Patients 65+ who consult their GP as part of an annual consultation for a chronic condition will be informed about the study in the waiting room and asked to complete a questionnaire in the waiting room based on the validated Visual functioning Questionnaire 25 (53). The questionnaire measures the dimensions of self-reported vision-targeted health status that are most important to individuals who have chronic eye diseases. A dedicated staff or GP will examine the vision according to the guidelines formulated in the model. The specific examination cannot be reported until the phases I+II have been completed, but we assume that an ordinary vision test, visual fields and contrast vision as well as a function test will be included.

If visual impairment is detected, the patient will undergo further examinations assessed by an ophthalmologist. At present time we assume that measurement of the visual acuity, tonometry, macular- and parapapillary OCT-scans and fundus photographs could be part of the extended examinations, but this is also part of Phase I+II to establish. This will function as a reference standard and allow us to study the prevalence of visual impairments as well as eye diseases and study predictor's for visual impairment as well.

Due to the Danish registers, it is possible to follow the cohort for a long period. This follow-up study is not part of the present project, but will be planned later.

Analysis

We will produce a variety of qualitative and quantitative data in the study, which will be analysed and disseminated accordingly by researchers with extensive experience in qualitative and quantitative analysis, respectively. The analytical process will be carried out iteratively, which covers analytical steps taken between each of the three project phases to ensure appropriate adjustments in the design of the intervention model (58).

Ultimo phase I, the empirical data produced in the phase will be analyzed through a thematic analysis, which will identify the primary issues of concern from all the perspectives of the various stakeholders (59). The findings from the analysis will form the foundation for the consecutive content workshops in Phase II.

Patients' and relatives' experiences of visual impairment are important to incorporate in the intervention design, and a macro-analytical approach is therefore pursued in synthesizing the patients' experience of early signs of vision loss and screening for vision loss, whereby this information is placed within cross-disciplinary theories. The study will focus on the notion of the loss of vision, highlighting the intricate encounters of individual senses, clinical practice, cross-sectorial collaborations and political health-economies. This macro-focus is complemented by attention to the micro-interactional processes of daily life (60). Here, the study will be adding a phenomenological theoretical (61) locus on the individual grounded in specific perceptions and bodily experiences (62) and the immediate struggle in the face of vision loss.

In Phase III, the analysis of the feasibility study in general practice will be structured according to the programme theory to identify how and if the activities in the intervention model lead to the intended outputs and outcomes (63).

All formal interviews will be audio-recorded and transcribed following a project guideline to ensure uniformity. The three phases will produce observations and informal talks, which will be documented through field-notes and pictures. The qualitative data will be analyzed thematically (59,64) with special attention to how the daily practice of care and clinical work is performed and the social interactions they encompass (65,66). The three workshops in Phase II will be documented through graphic facilitation, researcher field-notes and pictures.

The questions in the questionnaire for the feasibility test will be chosen based on the insights from Phase I+II to ensure relevance and accuracy.

Ethics and dissemination

Ethical issues will be a primary consideration at all levels of the study both when involving patients in the participatory design and during the cohort-study. The study is registered in the records of research projects containing personal data at University of Copenhagen (J.nr: 514-0701/22-3000). It will be conducted according to the ethical standards of the Helsinki Declaration and GDPR-legislation.

In data production, all participants will be asked to read and sign a consent form regarding their specific participation and kind of information, including how we will handle the information provided to us as, well as information on how to withdraw consent at a later stage. In the qualitative data production, we will produce photographic and graphic material, which requires further ethical reflections in terms of anonymization.

The cohort study involves a risk of over-diagnostic practice due to the tests and screening involved (67). Any potential harms, over-diagnosis, labelling effect and consequences of receiving the intervention will be scrutinized during Phase 1+2+3 (68). Age-related visual impairment diagnoses including glaucoma and AMD meet the requirements for screening formulated by WHO (69).

During the analysis, both benefits and harms of the intervention will be investigated and presented as results. Results will be published in peer-reviewed journals, preferably open-access. Patients, relatives and health professionals are invited in as co-authors where relevant. We will present our results in relevant fora nationally and internationally (conferences, annual meetings, etc). Additionally, we will organize a symposium directed at stakeholders from health and social care sector and employers. The participants from the three content-developing workshops in Phase II will be invited to participate in the symposia and share their experiences of being part of the research process. For communication to lay persons, we will produce a podcast on sensory loss in old age focused on vision and participate in the yearly Danish democracy and community festival "*Folkemødet",* which has a specific focus on communicating public health science.

The proposed study is relevant for ensuring kind and empathic care (70,71) with time to guide and comfort patients (72). This requires knowledge about how the patient experiences visual impairment as well as identification of the current challenges in the health services provided, which we aim to improve following the DETECT intervention. Specifically relevant in this study is the focus on general practice in relation to visual impairment, which is currently an understudied area.

Implications

Collectively, the output of intervention will help us understand, how to support and treat patients with impaired vision and to define an expedient role for general practice. In this respect, adding knowledge on the GP perspective will strengthen the feasibility of the intervention. The development of a co-designed intervention aimed at both patients and GPs can have an important impact on the delivered quality in the diagnosis and management of patients with visual impairment in primary care.

Authors Contributions

FBW, ABRJ, SR & CTS developed the original idea for the study. CTS wrote first draft of the protocol. CTS, ABRJ, SR, FBW, MHJ & OHM were primary in developing the methodological framework for the study. DBH, MDC, LK & MK provided detailed information regarding clinical procedures and ophthalmological expertise. MHJ & FBW performed the initial literature search. All authors critically reviewed and revised the initial draft and approved the final version of the manuscript.

Conflicts of interest

None to declare

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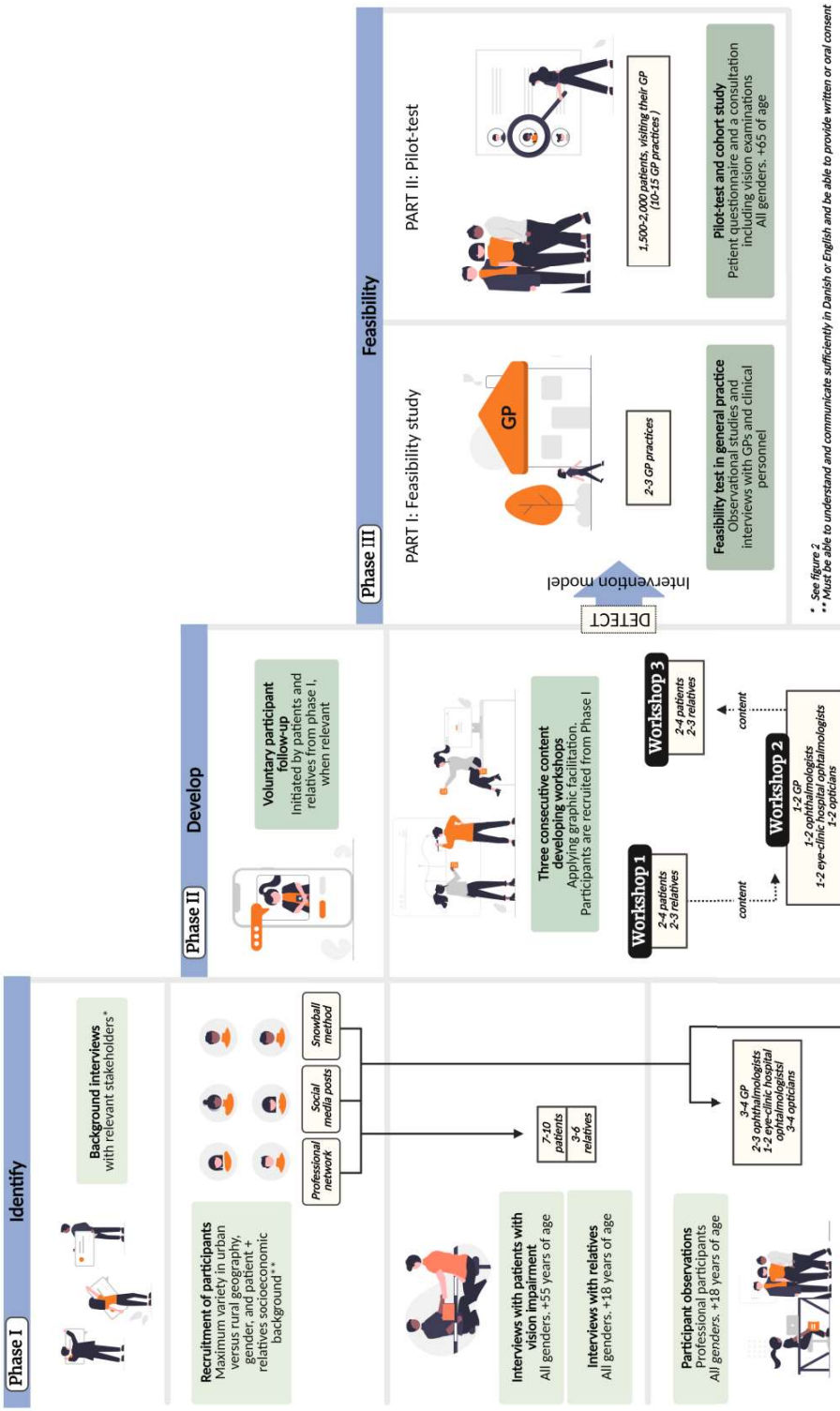
Phase I
Identify
Background interviews
with relevant stakeholders*
Recruitment of participants
Maximum variety in urban versus rural geography, gender, and patient + relatives socioeconomic background**
Professional network
Social media posts
Snowball method
Interviews with patients with vision impairment
All genders. +55 years of age
7-10 patients
3-6 relatives
Interviews with relatives
All genders. +18 years of age
Phase II
Develop
Voluntary participant follow-up
Initiated by patients and relatives from phase I, when relevant
Three consecutive content developing workshops
Applying graphic facilitation.
Participants are recruited from Phase I
Workshop 1
2-4 patients
2-3 relatives
content
Workshop 2
1-2 GP
1-2 ophthalmologists
1-2 eye-clinic hospital ophtalmologists
1-2 opticians
content
Workshop 3
2-4 patients
2-3 relatives
Participant observations
Professional participants
All genders. +18 years of age
3-4 GP
2-3 ophthalmologists
1-2 eye-clinic hospital ophtalmologists
3-4 opticians
16-24 older adults
Focus-group interviews
All genders. +55 years of age
DETECT
Intervention model
Phase III
Feasibility
PART I: Feasibility study
GP
2-3 GP practices
Feasibility test in general practice
Observational studies and interviews with GPs and clinical personnel
PART II: Pilot-test
1.500-2.000 patients, visiting their GP (10-15 GP practices)
Pilot-test and cohort study
Patient questionnaire and a consultation including vision examinations
All genders. +65 of age
* See figure 2
** Must be able to understand and communicate sufficiently in Danish or English and be able to provide written or oral consent

BMJ Open

DETECT – DEveloping and testing a model to identify preventive vision loss among older paTients in gEneral praCTice: Protocol for a complex intervention in Denmark

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DETECT – DEveloping and testing a model to identify preventive vision loss among older paTients in gEneral praCTice: Protocol for a complex intervention in Denmark

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Abstract

Introduction: The number of people living with visual impairment is increasing. Visual impairment causes loss in quality of life and reduce self-care abilities. The burden of disease is heavy for people experiencing visual impairment and their relatives. The severity and progression of age-related eye-diseases are dependent on the time of detection and treatment options, making timely access to health-care critical in reducing visual impairment. General practice plays a key role in public health by managing preventive healthcare, diagnostics, and treatment of chronic conditions. General practitioners (GPs) coordinate services from other healthcare professionals. More involvement of the primary sector could potentially be valuable in detecting visual impairment.

Methods: We apply the Medical Research Council (MRC) framework for complex interventions to develop a primary care intervention with the GP as a key actor, aimed at identifying and coordinating care for patients with low vision. The development process will engage patients, relatives and relevant health-professional stakeholders. We will pilot-test the feasibility of the intervention in a real-world general practice setting. The intervention model will be developed through a participatory approach using qualitative and creative methods such as graphic facilitation. We aim to explore the potentials and limitations of general practice in relation to detection of preventable vision loss.

Ethics and dissemination: Ethics approval is obtained from local authority and the study meets the requirements from the Helsinki declaration. Dissemination is undertaken through research papers and to the broader public through podcasts and patient organizations.

Strengths and limitations of this study

1. Visual impairment and vision loss are important health problems, but the role of general practice in relation to detection of visual impairment remains unclear. Through the Medical Research Council framework for complex interventions, this study seeks to unfold the potentials and limitations of the GP's role concerning visual impairment and vision loss
2. The study applies a participatory approach and explores the method of graphic facilitation to engage patients, relatives, GP's and other health professionals in the development of the intervention

3. The intervention will be tested in a real-world general practice setting in Denmark, which will ensure relevance and long-term acceptability of the intervention model
4. Limitations include that the intervention is in the pilot phase and will need to be tested in a larger scale at a later stage before wider implementation can be initiated

Introduction

It is estimated that 2.2 billion people have impaired vision, and of these, at least 1 billion people have a vision loss that could have been prevented or reduced by earlier detection or by access to treatment (1). The most common causes of moderate to severe visual impairment are uncorrected refractive errors, un-operated cataract, age-related macular degeneration (AMD), glaucoma and diabetic retinopathy (2). Also in affluent welfare states such as Denmark – constituting the setting of this study – visual impairment is a problem.

The incidence of visual impairment increases with age, and due to the sociodemographic trajectory of an increasing elderly population, the prevalence of patients with visual impairment will increase (3). Timely access to health care has a major influence on the progression of eye conditions (1,2). The consequences of vision loss significantly affect the person's quality of life (4–6), dependence (7) and increases the risk of recurrent falls and fractures, which is a significant threat to mobility in old age (8–12). A YouGov poll showed that sight was by far the sensory function, people fear losing the most (13). Vision loss can result in worsened mental health (14,15), cognition (16,17) and social functioning (4). Disease progression can be complicated by other chronic conditions (18) and can complicate management of multimorbidity due to decreased self-care, ability to visit clinics and adherence to medication. Finally, vision loss can increase the risks of placement in nursing homes (19,20). Thus, visual impairment and loss has great impact on the individual, their relatives (21,22), society in general and on the healthcare system.

General practice and visual impairment

GPs handle preventive healthcare, diagnostics, treatment and care of chronic conditions as well as coordinate services from various healthcare professionals (23). In the Global North, the GPs handle the majority of all medical matters. A survey set in English general practice from 1998 concluded that eye problems, including undiagnosed glaucoma and AMD, were quite frequent among elderly patients consulting their GP (24). One study found that patients were more likely to have their eyes checked if their GP suggests it (25). Additionally, an increased focus on eye health in at-risk

populations in general practice is suggested to be more effective for early detection than broader screening programs (26,27). However, a recent UK-based survey of GPs indicated that although up to five percent of the primary consultations were eye-related, GPs ability to identify red flags was low (28). The literature points to a gap where, even though patients are in contact with their GP concerning symptoms related to their vision, an unidentified number of patients may suffer from unrecognized visual impairment that is not detected in general practice.

Collaboration across healthcare professions

Since vision problems are rarely detected in general practice, the need for research into how patients and health professionals collaborate to identify and manage visual impairment becomes a relevant matter. This is in line with a recent Cochrane review, which concludes that future research should look at optimized primary care-based vision screening interventions (29). Patients with visual impairment often have contacts with many different healthcare professionals (30). It is therefore important to incorporate collaboration across health professions and sectors in a GP intervention aimed at improving identification of patients with visual impairment.

Optometrists constitute an occupational group who may be the first line of contact for some patients who experience visual changes. Optometrists will in most cases operate independently without a formal collaboration with other health professionals such as GPs (31). Given the optometrists contact with the patients and level of equipment for measuring vision and evaluating the eye, they pose a potentially important resource when collaboration across healthcare professions is rethought and are therefore important to include in the study. Their commercial agenda may influence their work and this will be evaluated in the collaboration (32,33).

Aim and objectives

In this study, we aim to develop a health intervention in a Danish general practice setting to improve the detection and care of visual impairment. The patient target group is middle-aged and older adults and their relatives, with GP's constituting the primary professional target group. We define visual impairment broadly to be the patient experience of symptoms related to vision and findings identified by health professionals – such as reduced vision field – not yet experienced by the patient, but a serious threat to patient vision. Visual impairment is in this respect not connected to specific diagnoses, but as previously stated, we assume frequent eye-diseases such as glaucoma and AMD will be well represented.

The overall aim of DETECT is thus to:

1. Develop an intervention in general practice aimed at identifying visual impairment among elderly patients with chronic conditions.
2. Test the feasibility of the intervention model in general practice with a focus on ensuring improved patient support and education.

Methods and analysis

The study will be conducted in Denmark and is thus inscribed in a Scandinavian health system with universal access to health care. The general health status in Denmark is relatively high, and as far as vision is concerned, the incidence of legal blindness has decreased along with improved treatment options (34). The average life expectancy has increased over the last 70 years, which is positive, but it also entails a rise in age-related sight-threatening eye diseases such as glaucoma and AMD (35). Despite the decreasing incidence of legal blindness due to AMD, many patients are diagnosed late with irreversible vision loss. It seems relevant to diagnose eye diseases earlier and optimize the coordination of care. It is difficult to provide an exact number of people in Denmark who live with visual impairment. A national survey of health, quality of life and morbidity from 2007 shows that 3.8% of the population over 60 reported difficulties in reading a newspaper text (36), while the Danish Eye Association estimate that 50.000 people in Denmark above 60 years are blind or visually impaired (37) (total population 60+: 1.554.542 (38)).

In Denmark, the GP is the patient's primary entry point to the healthcare system, and the GP treats 90% of all medical cases (23). All Danes are assigned to a default general practice, and as many as 80% consult their GP at least annually, with an increased frequency among patients aged 50 or older. People with chronic conditions are offered an annual health check at their GP. A Danish survey from 2019 showed that 82.4% of men and 86.7% of women had their vision measured at their GP within the last three years (39). However, these figures are from 2010 to 2017. In 2017, regulations regarding driving licenses were changed, resulting in vision being measured only every 15 years. This may result in a lower frequency of vision acuity measurements at the GP today, but from the 2017 figures we can assume that the practice of performing vision measurements during the annual consultation for older adults is a well-known procedure.

Ophthalmologists can diagnose, treat and carry out the necessary checks of e.g., glaucoma and atrophic AMD in the primary sector. If indicated, patients are referred to secondary care in the hospitals´ eye departments. Examples of referral indications may be neovascular AMD, proliferative diabetic retinopathy and medically uncontrollable glaucoma. At the hospitals, ophthalmologists

work publicly funded and university hospital clinics have an obligation to do research within the field.

Consultations with the GP or ophthalmologist are tax financed and without an out-of-pocket fee to patients (40,41). Hospital-based eye clinics are also free of charge, but the patient must be referred by a primary sector ophthalmologist for treatment. In cases of acute vision loss or pain, patients can be seen directly in the emergency room and referred from there to the on-call ophthalmologist in the hospital eye department. Anyone can book an appointment with the ophthalmologist in the primary sector without a referral, but due to a low number of ophthalmologists compared to the increasing demand, it is often difficult to book a consultation within a reasonable time frame and geographical distance. On the other hand, the GP must be available to all patients inscribed in his/her practice, and have an in-depth knowledge of the patient's general health and condition. The GPs therefore seem to be in an ideal situation to identify visual impairment and coordinate the management.

It's estimated that around 2000 optometrists operate in Denmark (total population 5.8mill.) and opticians shops can be found in most smaller cities, making it accessible even in rural areas to visit an optician shop (42,43). In most optician shops, it is free of charge to have vision tested. Many optometrists offer intraocular pressure measurements and fundus photographs as additional procedures for a fee. Optometrists are thus a professional stakeholder that we find interesting to explore further.

Study phases

We apply the Medical Research Council (MRC) guidance on developing, testing and evaluating complex interventions (44,45). To operationalize the framework for complex interventions, we apply a temporal structure from the tradition of human-centered design to divide the project cycle into three main phases: (I) identify the problem, (II) develop the model and (III) test the feasibility of the model.(46) Phase I+II focus on intervention development applying qualitative methods and Phase III aims to first pilot-test the intervention for feasibility and following implement it broader in a cohort study to measure effect.

The intervention explores what patients, carers and professionals perceive as pivotal to improve regarding detection, navigating care and health services and support possibilities for people living with visual impairment. We are explicitly reflective on, how process and product are interwoven and to a very high extent dependent on the context it unfolds within (44,47). Following a structured and well-documented design process we identify the changes made and insights produced (see Figure 1).

[INSERT Figure 1[1]. *Figure 1: DETECT overall study design and participants engaged.*]

Phase I: Identify –Identifying key issues to address in the health intervention

The aim of Phase I is to explore the problem we are addressing. We will perform a literature search on detection of eye-diseases in general practice and conduct background interviews with a broad selection of relevant stakeholders to help us map the current practice in detecting and diagnosing eye conditions across sectors in the health care system (see Figure 2).

[INSERT figure 2. *Figure 2: Stakeholders identified to participate in a background interview*]

An essential element in human-centered design processes is to create understanding and empathy for the end-user (48,49) – in our case people living with visual impairment and their relatives. We aim to incorporate a wide spectrum of eye-diagnoses and develop a model to identify and diagnose visual impairment that works from the onset of the patient's early symptoms, such as stumbling over doorsteps, difficulties in reading, distorted vision or difficulties related to the transition from dark to light spaces and vice versa. The intervention aim of increased patient support also includes support of relatives, who carries a large part of the burden of the disease and may experience stress and depression due to their loved one's visual impairment (50).

Patient and public involvement in Phase I

Patients, relatives and professionals will be involved by providing their perspectives in various stages of the study and co-design core elements of the model constituting the intervention. The patient engagement process is informed by a thorough report produced by the Danish Center for Social Science Research on older adults with visual impairment and vision loss (35). The report underlines the need for increased knowledge on how visual impairment affects patients' every-day life in all aspects. The experiences, needs, preferences, and values of patients and relatives will thus be explored (51). See Figure 1 for an overview of the involvement of participants across the three project phases.

[1] Figure 1+2 were created with BioRender.com

In Phase I, we perform semi-structured interviews with patients and relatives, preferably in their homes to gain an insight in their experiences in the context in which they occur. Here we focus on the patient journey from the time patients experience symptoms leading to a diagnosis and handling life afterwards with a diagnosis. After the interview, patients and relatives are encouraged to contact the researcher if they would like her/him to participate in e.g., a visit to the ophthalmologist or if they have further input or concerns at a later stage.

We will furthermore perform focus-group interviews with older adults to investigate (1) the expectations to vision in old age and (2) which health professionals' older adults identify as relevant when they experience vision changes. The focus-group interviews supplement the interviews with patient and relative with a view to gaining insight into the social norms and prominent attitudes towards visual impairment among older adults. The participants in the focus-group interviews are asked to complete the validated Visual Function Questionnaire-25 to provide more individual knowledge about the participants own perception of their vision function (52).

Through participant observations, we will generate knowledge on the everyday working environment and challenges that health professionals, private optometrists and communal workers navigate in concerning people with visual impairment (53).

Phase II: Develop – Developing the intervention-model

In Phase II, we operationalize the insights from Phase I. This will be done through three consecutive content-developing workshops using the creative method of graphic facilitation (54).

Graphic facilitation is well suited when elaborating on ideas and problem-solving processes because it allows for a transparent process open to multiple agendas. The method can be relevant for redistributing power and expertise in a co-design activity and the physical product of the three content workshops will act as design principles for the intervention. (55,56). CTS facilitates the workshops and we invite a graphic facilitator to analogue draw and write inputs from the participants on a wall-to-wall paper during the workshops. The graphic recordings from the three workshops constitute a collective overview of core elements to include in the intervention-model (see description below and figure 1 for specifics on the workshop content). Choosing a visual method to engage participants could seem an unusual choice in a project focusing on visual impairment and vision loss. However, the participants are not blind. They live with a visual impairment, which poses a range of consequences and constraints in their every-day life, but it does not prevent them from being able to participate in a graphic facilitated workshop. If needed, relevant aids will be provided – in example to enlarge the graphic recordings on a tablet

Flow of the three workshops: The graphic facilitator and project researchers develop a template for the workshops. Participants for the workshops are recruited among participants in phase I.

Workshop 1:

In this workshop, the graphic facilitator engages patients and relatives to formulate a graphic recording on what is lacking in the identification, diagnosis and patient support concerning visual impairment.

Workshop 2:

The focus for this workshop is to include perspectives from relevant health professionals in the design phase. The health professionals are asked to identify possibilities and barriers of an intervention concerning vision impairment in general practice, including a discussion on key eye examinations and measures that would be feasible in a general practice setting as well as to identify the most relevant prevalent progressive severe eye diseases.

Workshop 3:

Aims to synthetize the knowledge produced in the previous two workshops by formulating the specific activities, concrete consultation type and identify final intervention effect measurements. This also includes choosing the relevant guidelines for screening and diagnosing to apply in the intervention. Participants are GP's and project researchers. Other stakeholders will be invited if relevant based on the insights from workshop 1+2.

Phase III: Feasibility– Feasibility test in general practice

Part 1: Pilot-test

The intervention model will be first be validated and adjusted accordingly by patient representatives and ophthalmologists. The model will then be tested in a general practice setting to establish face validity and adjust according to the experiences. The model must be clinically relevant and feasible for implementation in a clinical practice. Data production continues in this phase through observational studies and interviews with GPs to disseminate the experiences with the model in general practice and whether the model can be part of improved collaboration between health professionals.

Part 2: Cohort study

Based on findings from the pilot-test, we expand the intervention by including ten to fifteen GP practices in the Capital and Zeeland Region, Denmark to participate in testing the GP's possibilities and barriers to detect visual impairment and vision loss. According to previous literature (36), we

need to include 1500-2000 patients in general practice aged 65 or older to identify 150-200 with visual impairment. The practices will receive the developed intervention-model and recruit in up to 18 months. Patients 65+ who consult their GP as part of an annual consultation for a chronic condition will be informed about the study in the waiting room and asked to complete a questionnaire based on the validated Visual functioning Questionnaire 25 (52). The questionnaire measures the dimensions of self-reported vision-targeted health status that are most important to individuals who have chronic eye diseases. A dedicated staff or GP will examine the vision according to the guidelines formulated in the model. If visual impairment is detected, the patient will undergo further examinations assessed by an ophthalmologist.

The specifics of the examinations in general practice and at an ophthalmologist cannot be reported until the phases I+II have been completed, since these are to be developed in the co-design process. At present we assume an ordinary vision test, visual fields and contrast vision as well as a function test could be included in the GP setting. We assume that measurement of the visual acuity, tonometry, macular- and parapapillary OCT-scans and fundus photographs could be part of the extended examinations at an ophthalmologist. An important outcome of Phase II is thus detailed information on effect measurements, chosen guidelines and possibly a narrowed focus on specific eye-diseases to address in the intervention. The results from the cohort-study will function as a reference standard and allow us to study the prevalence of visual impairments as well as eye diseases and study predictor's for visual impairment as well. Due to the Danish registers, it is possible to follow the cohort for a long period (57). This follow-up study is not part of the present project, but will be planned later.

Analysis

The analytical process will be carried out iteratively, which covers analytical steps taken between each of the three project phases to ensure appropriate adjustments in the design of the intervention model (58).

All formal interviews from the study will be audio-recorded and transcribed following a project guideline to ensure uniformity. The three phases will generate observations and informal talks, which will be documented through field-notes and pictures. Details on the analytical steps are illustrated in figure 3.

[INSERT FIGURE 3. *Figure 3: Analytical steps*]

Ethics and dissemination

Ethical issues will be a consideration at all levels of the study both when involving patients in the participatory design and during the cohort-study. The study is registered in the records of research projects containing personal data at University of Copenhagen (J.nr: 514-0701/22-3000). It will be conducted according to the ethical standards of the Helsinki Declaration and GDPR-legislation. Ethical approval was waived by the Danish National Ethical Research Committee because no bio-material is included in the study.

In data production, all participants will be asked to read and sign a consent form regarding their specific participation and kind of information, including how we will handle the information provided to us as, well as information on how to withdraw consent at a later stage. In the qualitative data production, we will produce photographic and graphic material, which requires further ethical reflections in terms of anonymization.

The cohort study involves a risk of over-diagnostic practice due to the tests and screening involved (59). Any potential harms, over-diagnosis, labelling effect and consequences of receiving the intervention will be scrutinized during the study (60). Age-related visual impairment diagnoses including glaucoma and AMD meet the requirements for screening formulated by WHO (61). During the analysis, both benefits and harms of the intervention will be investigated and presented as results. Results will be published in peer-reviewed journals, preferably open-access. Patients, relatives and health professionals are invited in as co-authors where relevant. We will present our results in relevant fora nationally and internationally (conferences, annual meetings, etc.). Additionally, we will organize a symposium directed at stakeholders from health and social care sector and employers. The participants from the three content-developing workshops in Phase II will be invited to participate in the symposia and share their experiences of being part of the research process. For communication to lay persons, we will produce a podcast on sensory loss in old age focused on vision and participate in the yearly Danish democracy and community festival "*Folkemødet",* which has a specific focus on communicating public health science.

The proposed study is relevant for ensuring kind and empathic care (62,63) with time to guide and comfort patients (64). This requires knowledge about how the patient experiences visual impairment as well as identification of the current challenges in the health services provided, which we aim to improve following the DETECT intervention. Specifically relevant in this study is the focus on general practice in relation to visual impairment, which is currently an understudied area.

Implications

Collectively, the output of intervention will help us understand, how to support and treat patients with impaired vision and to define an expedient role for general practice. In this respect, adding knowledge on the GP perspective will strengthen the feasibility of the intervention. The development of a co-designed intervention can have an important impact on the delivered quality in the diagnosis and management of patients with visual impairment in primary care.

Authors Contributions

FBW, ABRJ, SR & CTS developed the original idea for the study. CTS wrote first draft of the protocol. CTS, ABRJ, SR, FBW, MHJ & OHM were primary in developing the methodological framework for the study. DBH, LK & MK provided detailed information regarding clinical procedures and ophthalmological expertise. MHJ & FBW performed the initial literature search. All authors critically reviewed and revised the initial draft and approved the final version of the manuscript.

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Conflicts of interest

None to declare

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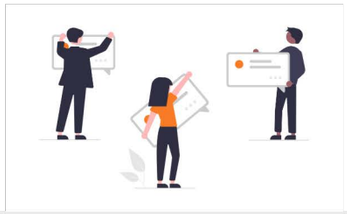
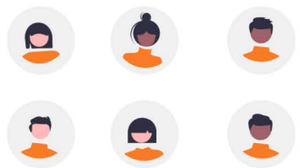
Phase I — Identify

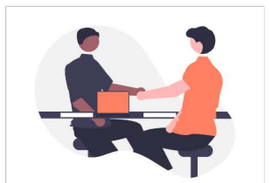


Background interviews
with relevant stakeholders*

Recruitment of participants
Maximum variation in urban versus rural geography, gender, and patient + relatives socioeconomic background**



Professional network | *Social media posts* | *Snowball method*

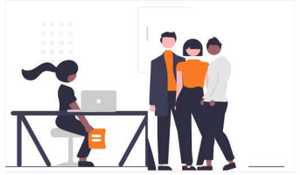


Interviews with patients with vision impairment
All genders. +55 years of age

7-10 patients
3-6 relatives

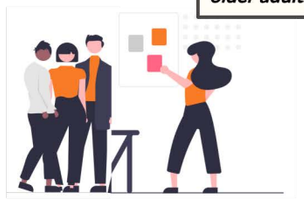
Interviews with relatives
All genders. +18 years of age

Participant observations
Professional participants
All genders. +18 years of age



3-4 GP
2-3 ophthalmologists
1-2 eye-clinic hospital ophthalmologist
3-4 optometrists

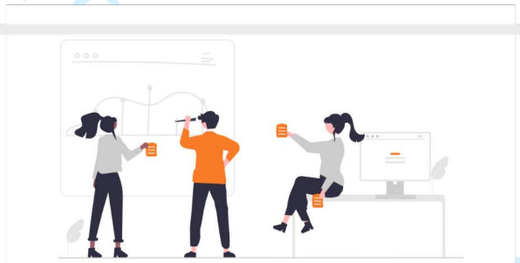
Focus-group interviews
All genders. +55 years of age



16-24 older adults

Phase II — Develop

Voluntary participant follow-up
Initiated by patients and relatives from phase I, when relevant



Three consecutive content developing workshops
Applying graphic facilitation.
Participants are recruited from Phase I

Workshop 1
2-4 patients
2-3 relatives

Workshop 3
1-2 GP
DETECT Project group

content

content

Workshop 2
1-2 GP
1-2 ophthalmologists
1-2 eye-clinic hospital ophthalmologist
1-2 optometrists

Phase III — Feasibility

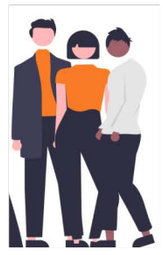
PART I: Feasibility study

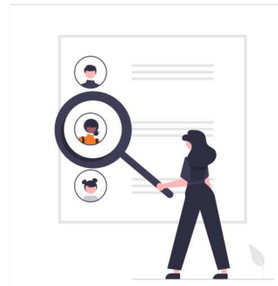
DETECT Intervention model

2-3 GP practices

Feasibility test in general practice
Observational studies and interviews with GPs andGP clinical personnel

PART II: Pilot-test





1,500-2,000 patients, visiting their GP (10-15 GP practices)

Pilot-test and cohort study
Patient questionnaire and a consultation including vision examination
All genders. +65 of age

* *See figure 2*
** *Must be able to understand and communicate sufficiently in Danish or English and be able to provide written or oral consent*

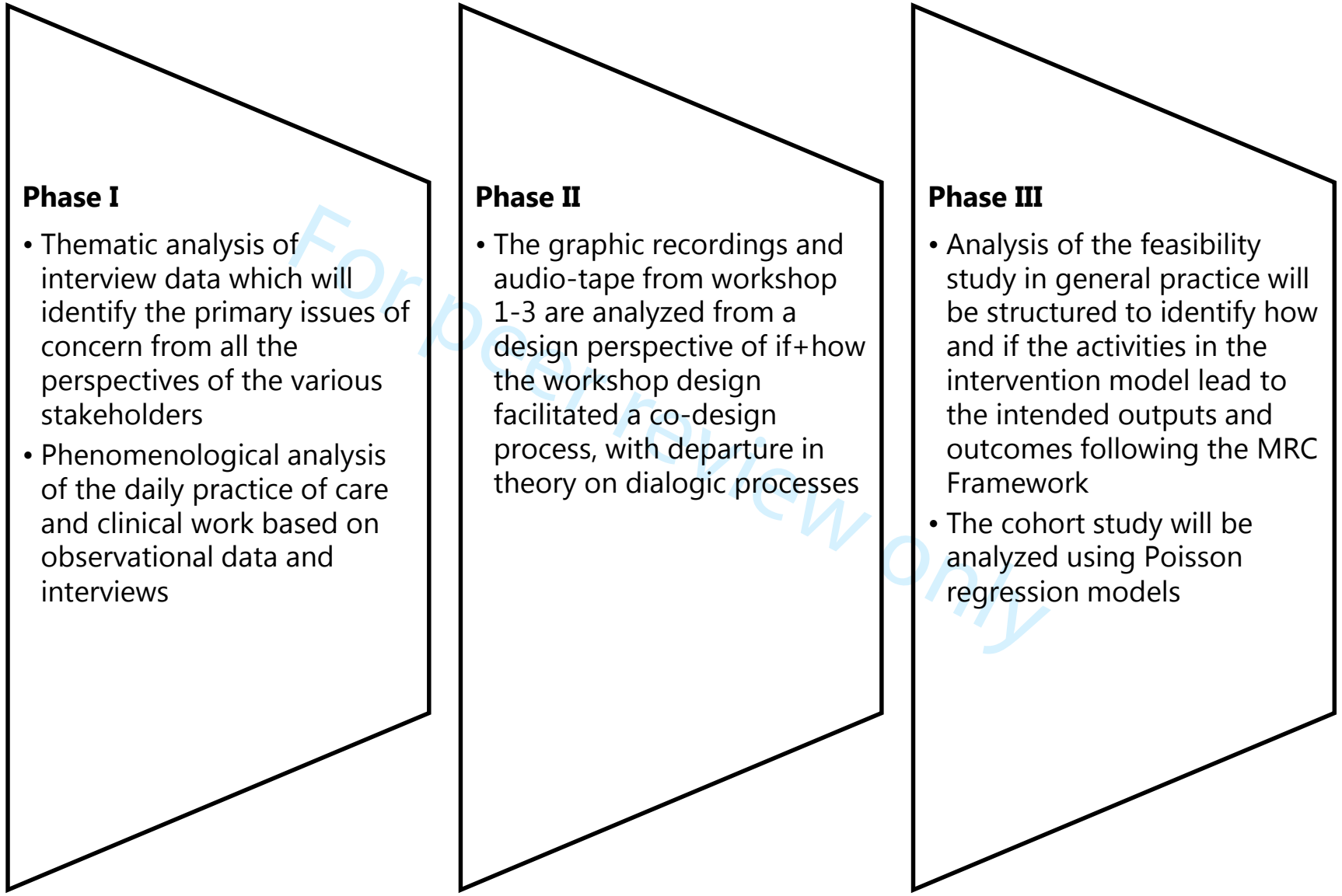


Figure 3: DETECT Analytical steps