

Development of the Complex Intervention

Physical Activity to reduce Vascular Erectile Dysfunction

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DEVELOPMENT OF THE COMPLEX INTERVENTION:

PHYSICAL ACTIVITY TO REDUCE
VASCULAR ERECTILE DYSFUNCTION

**BY
HELLE GERBILD**

DISSERTATION SUBMITTED 2021



AALBORG UNIVERSITY
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DEVELOPMENT OF THE COMPLEX INTERVENTION:

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CV

Helle Gerbild became a physiotherapist in 1984 and has a clinical background in municipal rehabilitation. In 2008, Gerbild graduated as Master in Health Science at University of Southern Denmark, and became a Senior Lecture at UCL University College in Odense. In 2011, Gerbild became a specialist in sexology at the Danish Association for Clinical Sexology, and she became a urological, gynaecological, sexological physiotherapist working part time in clinical practice in 2013. In 2015, Gerbild graduated as a Master in Sexology at Aalborg University, where she was enrolled as a PhD fellow in February 2019. Using review, qualitative, quantitative and psychometrical methods her doctoral research focused on 'Development of the Complex Intervention Physical Activity to reduce Vascular Erectile Dysfunction' (PAVED), including five project papers. Gerbild has reviewed the level of physical activity needed to reduce vascular erectile dysfunction (ED). Furthermore, she has explored the acceptance and perspectives among men concerning health professionals' address of and communication about sexuality, ED and information in regards to PAVED. In addition, Gerbild has translated, adopted and psychometrically tested a questionnaire, the Danish version of Healthcare Students' Attitudes towards Addressing Sexual Health (SA-SH-D). Gerbild used the SA-SH-D in a national survey of Danish healthcare students' attitudes and readiness to address sexual health in their future profession.

ENGLISH SUMMARY

Background: For many men worldwide erectile dysfunction (ED) is a common problem. The most common form of ED is vascular ED – caused by risk factors such as physical inactivity, obesity, hypertension, metabolic syndrome and cardiovascular diseases. It is evident, that physical activity can prevent and reduce vascular ED; however, regarding the intervention ‘Physical Activity to reduce Vascular Erectile Dysfunction’ (PAVED), the level of physical activity needed to reduce vascular ED was unclear. ED is common for men with cardiovascular diseases and physical activity is a core intervention in cardiovascular rehabilitation. Cardiac health professionals rarely provide information about ED or its relation to physical activity. The communicative component: information about PAVED (i-PAVED) therefore includes professional-patient communication about ED. Thus, there was a need to explore acceptance and perspectives among men with cardiovascular diseases (potential receivers of PAVED) regarding health professionals’ address of and communication on sexuality, ED, and i-PAVED. In addition, Danish health professional students’ (potential future providers of PAVED) attitudes towards addressing sexual health were unclear. To provide i-PAVED for men with cardiovascular risk factors for ED, it seems important to develop the complex intervention PAVED.

Aim: The aim of this PhD project was to develop the complex intervention ‘Physical Activity to reduce Vascular Erectile Dysfunction’ (PAVED). The development process included:

- reviewing knowledge about the physical activity level needed to reduce erectile dysfunction (ED) for men with physical inactivity, obesity, hypertension, metabolic syndrome, and/or cardiovascular diseases
- exploring how acceptance of cardiac health professionals’ address of sexuality, ED and i-PAVED can be identified in men’s narratives
- clarifying men's perspectives on cardiac health professionals' communication about i-PAVED
- translating and testing the Danish version of the questionnaire Students’ Attitudes towards addressing Sexual Health (SA-SH-D)
- Investigating of Danish health professional students’ attitudes towards addressing sexual health, and to assessing differences in perceived competence and preparedness between the professional programmes.

Methods: In **Study I**, a systematic review of the needed level of physical activity to reduce vascular ED was performed. In **Studies II and III**, individual interviews with men with cardiovascular diseases were analysed deductively and inductively. In **Study II**, a content analysis, using the Theoretical Framework of Acceptability (TFA), was applied in a concept-driven first step followed by a thematically data-

driven second step. In **Study III**, an interpretive data-driven thematic analysis was used. In **Study IV**, a translation and psychometric test of the Danish version of Students' Attitudes towards Addressing Sexual Health (SA-SH-D) was performed for use in **Study V**, which was a national survey of Danish health professional students' attitudes, competence and capacity to address sexual health in their professional work. Results: In **Study I**, supervised aerobic physical activity of moderate to high intensity, 40 minutes 4 times a week, could reduce vascular ED. **Study II** showed that men with cardiovascular diseases seemed to accept health professionals' address of sexuality, ED and i-PAVED, provided that health professionals are professional, educated and competent in the field of sexual health. In **Study III**, according to the men, ED was perceived as a major problem, and they wanted help to self-help, which may be possible with competent health professionals' communication about how to prevent, reduce and cope with ED - including i-PAVED. The men wanted health professionals' general information in groups, sexual counselling for individuals and couples and written material. In **Study IV**, the SA-SH-D was tested to be a valid and reliable questionnaire to measure health professional students' attitudes and perceived competence towards addressing sexual health in their future professional work. In **Study V**, a total of 584, equivalent to 48% (nursing 44%, occupational therapy 70%, physiotherapy 43%) responded. Mean total score ranged between 63.7-66.3 (± 8.3 -8.8), classifying students in the low end of the class as 'comfortable and prepared in some situations'. No clinically relevant differences were determined between the professional programmes with respect to perceived competences and preparedness to address sexual health.

Conclusion: In **Study I**, recommended physical activity to reduce vascular ED should include supervised training consisting of 40 minutes of aerobic exercise of moderate to high intensity 4 times a week. In **Study II**, men attending cardiac secondary prevention and rehabilitation programme seemed to prospectively accept health professionals' address of sexuality, ED and i-PAVED, provided that health professionals are professional, educated and competent in the field of sexual health. In **Study III**, regarding health professionals' communication, the men had perspectives on the questions of 'why', 'what', 'how' and 'which' that can be used to design the component i-PAVED. In **Study IV**, the questionnaire SA-SH-D was provided. In **Study V**, most Danish HP students reported positive attitudes and a need for basic knowledge, competence, communication training and education in the field of addressing sexual health.

Overall, across the included studies, the findings in this PhD project have contributed to developing an evidence and need-driven base for intervention studies regarding the complex intervention PAVED, together with increased understanding of the importance of educating future healthcare providers in sexual health.

DANSK RESUME

Baggrund: Erektile dysfunktion (ED) er et almindeligt problem for mange mænd verden over. Den mest almindelige form er vaskulær ED - forårsaget af risikofaktorer som fysisk inaktivitet, fedme, hypertension, metabolisk syndrom og hjertekarsygdomme. Der er evidens for, at fysisk aktivitet kan forebygge og reducere vaskulær ED, men i forhold til interventionen 'Fysisk Aktivitet der kan reducere Vaskulær Erektile Dysfunktion', på engelsk **Physical Activity to reduce Vascular ED (PAVED)**, var niveauet af fysisk aktivitet, nødvendigt for at reducere vaskulær ED, uklart. ED er almindelig for mænd med hjertekarsygdomme, og fysisk aktivitet er en central intervention i hjerterehabilitering. Sundhedsprofessionelle, der arbejder med hjertesygdom, informerer sjældent om ED eller sammenhængen med fysisk aktivitet. Den kommunikative komponent 'information om PAVED' (i-PAVED) inkluderer netop kommunikation om ED mellem den sundhedsprofessionelle og patienten. Således var der et behov for at undersøge accept og perspektiver blandt mænd med hjertekarsygdomme (potentielle modtagere af PAVED) vedrørende sundhedspersonalets adressering og kommunikation om seksualitet, ED og i-PAVED. Derudover var danske sundhedsprofessionelle studerendes (potentielle fremtidige formidlere af PAVED) holdninger til at samtale om seksuel sundhed underbelyst. For at formidle i-PAVED til mænd med kardiovaskulære risikofaktorer for ED, syntes det vigtigt at udvikle den komplekse intervention, PAVED.

Formål: Ph.d.-projektets formål var at udvikle den komplekse intervention 'Fysisk Aktivitet der kan reducere Vaskulær Erektile Dysfunktion' (PAVED). Udviklingsprocessen omfattede:

- tilvejebringelse af viden om det fysiske aktivitetsniveau, der er nødvendigt for at reducere erektil dysfunktion (ED) for mænd karakteriseret af fysisk inaktivitet, overvægt, hypertension, metabolisk syndrom og/eller hjertekarsygdomme;
- en undersøgelse af, hvordan accept af hjertesygdomssundhedsprofessionelles adressering af seksualitet, ED og i-PAVED kan identificeres i mænds narrativer;
- belysning af mænds perspektiver på hjertesygdomssundhedsprofessionelles kommunikation om i-PAVED;
- oversættelse og psykometrisk test af den danske version af spørgeskemaet '*Healthcare Students' Attitudes towards Addressing Sexual Health*' (SA-SH-D);
- undersøgelse af danske sundhedsprofessionelle studerendes holdninger til at adressere seksuel sundhed og vurdere forskelle i opfattede kompetencer og parathed mellem uddannelsesprogrammer.

Metoder: I **Studie I** blev der foretaget en systematisk gennemgang af det nødvendige niveau af fysisk aktivitet for at reducere vaskulær ED. I **Studie II and III** blev individuelle interviews med mænd med hjertesygdomme analyseret deduktivt og induktivt. I **Studie II** blev en indholdsanalyse og '*the Theoretical Framework of*

Acceptability' anvendt i et teoridrevet første trin, der blev efterfulgt af et tematisk datadrevet andet trin. I **Studie III** blev der anvendt en fortolkende datadrevet tematisk analyse. I **Studie IV** blev der udført en oversættende og psykometrisk test af den danske version af spørgeskemaet '*Health Care Students' Attitudes towards Addressing Sexual Health*' (SA-SH-D) til brug for **Studie V**, som var en national spørgeskemaundersøgelse af danske fremtidige sundhedsprofessionelle studerendes holdninger, kompetencer og kapacitet til at adressere seksuel sundhed i deres professionelle arbejde.

Resultater: I **Studie I** kunne superviseret aerob fysisk aktivitet af moderat til høj intensitet, 40 minutter 4 gange om ugen reducerer vaskulær ED. **Studie II** viste, at mænd med hjertekarsygdomme syntes at acceptere sundhedsprofessionelles adressering af seksualitet, ED og i-PAVED, forudsat at de sundhedsprofessionelle er professionelle, uddannede og kompetente inden for området seksuel sundhed. I **Studie III** opfattede mændene ED som et stort problem, og de ønskede 'hjælp til selvhjælp', hvilket kan være muligt med kompetente sundhedsprofessionelles kommunikation om, hvordan man kan forebygge, reducere og håndtere ED – inklusive i-PAVED. Mændene ønskede de sundhedsprofessionelles generelle information i grupper, seksuel rådgivning til enkeltpersoner og par samt skriftligt materiale. I **Studie IV** blev SA-SH-D testet til at være et validt og pålideligt spørgeskema til måling af sundhedsprofessionelle studerendes holdninger og opfattede kompetence til at adressere seksuel sundhed i deres fremtidige professionelle arbejde. I **Studie V** responderede i alt 584, svarende til 48 % (sygepleje 44 %, ergoterapi 70 %, fysioterapi 43 %). Den gennemsnitlige score varierede mellem 63,7-66,3, der klassificerede de studerende i den lave ende af kategorien: 'komfortable og forberedte i nogen situationer'. Ingen klinisk relevante forskelle blev fundet mellem de professionelle programmer i forhold til opfattet kompetence og parathed til at adressere seksuel sundhed.

Konklusion: I **Studie I** blev fysisk aktivitet til at reducere vaskulær ED anbefalet til at omfatte superviseret aerob fysisk aktivitet af moderat til høj intensitet, 40 minutter 4 gange om ugen. I **Studie II** syntes mænd, der deltog i hjerteforebyggelse og rehabilitering, prospektivt at acceptere sundhedsprofessionelles adressering af seksualitet, ED og i-PAVED, forudsat de sundhedsprofessionelles professionalisme, uddannelse og kompetence inden for feltet seksuel sundhed. I **Studie III**, vedrørende sundhedsprofessionelles kommunikation havde mændene perspektiver på spørgsmålene om 'hvorfor', 'hvad', 'hvordan' og 'hvilke', hvilke kan være anvendelige bidrag til design af komponenten i-PAVED. I **Studie IV** blev spørgeskemaet SA-SH-D tilvejebragt. I **Studie V** rapporterede de fleste danske sundhedsprofessionelle studerende om positive holdninger og behov for grundlæggende viden, kompetence, kommunikationstræning og uddannelse inden for seksuel sundhed. Samlet set har resultaterne i dette ph.d.-projekt på tværs af de inkluderede studier bidraget til at give et evidens- og behovsbaseret grundlag for interventionsstudier af den komplekse intervention PAVED, og har derudover øget forståelsen af vigtigheden af at uddanne fremtidige sundhedsprofessionelle i seksuel sundhed.

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PAPERS

The scientific work presented in this PhD was performed at the Department of Health Sciences Research Centre, UCL University College, Odense, Denmark and Center for Sexology Research, Department of Clinical Medicine at Aalborg University, Denmark.

The PhD thesis is based on five project papers:

- I. Gerbild H, Larsen CM, Graugaard C, Areskoug-Josefsson K. Physical Activity to Improve Erectile Function: A Systematic Review of Intervention Studies.
Published in: Sexual Medicine. 2018 Jun;6 (2):75-89 (1)
- II. Gerbild H, Areskoug-Josefsson K, Larsen CM, Laursen BS. Acceptability of Health Professionals' Address of Sexuality and Erectile Dysfunction - A qualitative Interview Study with Men in Cardiac Rehabilitation
Reviewed, revised and submitted January 2021 to Sexual Medicine (2)
- III. Gerbild H, Areskoug-Josefsson K, Larsen CM, Laursen BS. Developing the Communicative Component in the Complex Health Intervention: Physical Activity to reduce Vascular Erectile Dysfunction - a Qualitative Interview Study among Men in Cardiac Rehabilitation
Submitted December 2020 to Scandinavian Journal of Caring Science (3)
- IV. Gerbild H, Larsen CM, Rolander B, Areskoug Josefsson K. Healthcare Students' Attitudes towards Addressing Sexual Health in Their Future Professional Work: Psychometrics of the Danish Version of the Students' Attitudes towards Addressing Sexual Health Scale.
Published in: Sexuality and Disability. 2017;35(1):73-87 (4)
- V. Gerbild H, Larsen CM, Junge T, Laursen BS, Areskoug-Josefsson K. Danish Health Professional Students' Attitudes towards Sexual Health – A cross-sectional survey.
Accepted for publication in December 2020 in Sexual Medicine (5)

THESIS AT A GLANCE

The overall aim of this PhD project was the development of the complex intervention Physical Activity to reduce Vascular Erectile Dysfunction (PAVED) focusing on the following elements: Study I, evidence on the physical activity level needed to reduce vascular ED. Studies II and III, potential receivers' acceptance of and perspectives on health professionals' address, communication and information of PAVED. Study IV and V, potential future providers' capacity, attitudes, readiness and competence to address sexual.

Figure 1 shows the conducted studies contributing to the project development. Table 1 shows an overview of the included studies.

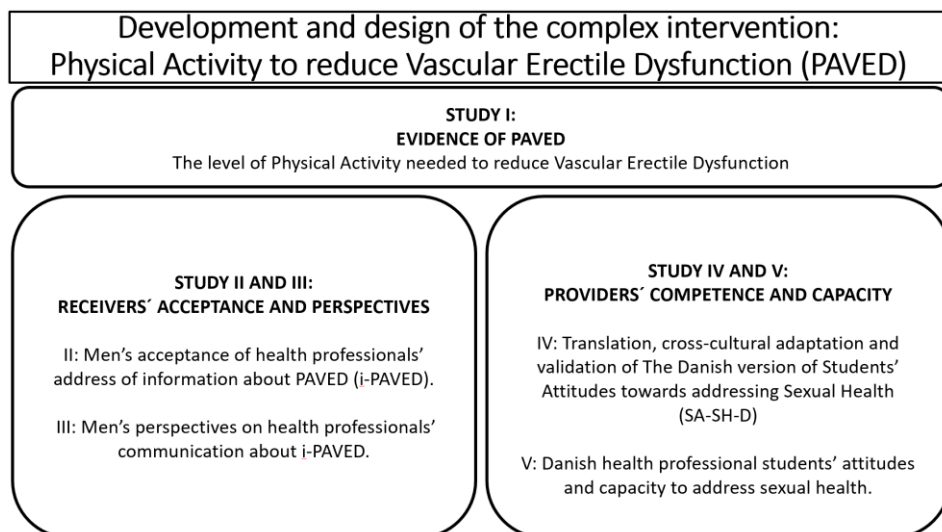


Figure 1. Conducted studies contributing to the project development.

Table 1. Overview of the five included studies

Study	Aim	Study design	Participants /data	Results and conclusion
I	To provide knowledge about the physical activity level needed to reduce erectile dysfunction (ED) ¹ for men with physical inactivity, obesity, hypertension, metabolic syndrome, and/or cardiovascular diseases.	Systematic review.	Research articles investigating physical activity as a possible treatment of ED caused by physical inactivity, obesity, hypertension, metabolic syndrome, and/or cardiovascular diseases. All available studies from 2006 through 2016 were checked.	Ten articles met the inclusion criteria. Physical activity to improve erectile function [reduce ED] is recommended to include supervised aerobic physical activity of moderate to high intensity, 40 minutes 4 times a week. Weekly exercise of 160 minutes for 6 months contributes to decreasing ED caused by physical inactivity, obesity, hypertension, metabolic syndrome, and/or cardiovascular diseases.
II	To explore how acceptance of cardiac health professionals' (HPs) ² address of sexuality, ED and i-PAVED ³ can be identified in men's narratives	In a content analysis, TFA ⁴ was applied in a concept-driven first step followed by a thematically data-driven	Twenty men in municipal cardiac secondary prevention and rehabilitation participated in individual qualitative interviews. A semi-structured	Men attending municipal cardiac secondary prevention and rehabilitation programmes seem to accept health professionals' address of sexuality, ED and i-PAVED, if HPs are professional, educated

¹ ED: erectile dysfunction

² HPs: Health Professionals

³ i-PAVED: information about Physical Activity to reduce Vascular Erectile Dysfunction

⁴ TFA: The Theoretical Framework of Acceptability

		second step.	interview guide was used. The first author conducted the interviews.	and competent in the field.
III	To clarify men's perspectives on cardiac HPs' communication about i-PAVED.	An interpretive data-driven thematic analysis was applied.		The men wanted HPs to communicate about ED, because ED was perceived as a major problem diminishing masculinity, affecting their relationship and tabooed by HPs. Men wanted help to self-help, which may be possible with the aid of competent HPs' communication about how to prevent, reduce and cope with ED – including i-PAVED. The men wanted HPs to give permission to talk about ED in various contexts: general information in groups, sexual counselling for individuals and couples, and written material. Men had perspectives on the questions of 'why', 'what', 'how' and 'which' regarding the way that HPs need to communicate about PAVED. These perspectives can be useful in designing the complex intervention PAVED.
IV	To translate and psychometrically test the Danish version of the questionnaire	Translation and psychometric testing of	Three translators. Committee review: the research group	The SA-SH-D had a Cronbach's alpha of 0.67. The content validity index showed

	Students' Attitudes towards Addressing Sexual Health (SA-SH-D) ⁵ .	a SA-SH-D.	and the three translators. Face validity: two groups of four to seven HP students; 40 students tested SA-SH-D.	high relevance (CVI ⁶ 0.82–1.0). Item scale correlation was satisfactory. The SA-SH-D is a valid and reliable questionnaire to measure HP students' attitudes towards addressing sexual health in their future profession.
V	To investigate Danish HP students' attitudes towards addressing sexual health. To explore differences in students' perceived competence depending on the students' educational programme.	A Danish national survey using the SA-SH-D.	584 students in their final semester in nursing, occupational therapy, and physiotherapy programmes.	Most of the HP students reported positive attitudes and a need for basic knowledge, competence, communication, training and education in the field of sexual health. No clinically relevant differences were determined between the professional programmes.

⁵ SA-SH-D: the Danish version of Students' Attitudes towards Addressing Sexual Health

⁶ CVI: Content Validity Index

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ABBREVIATIONS

CVI: Content Validity Index

ED: Erectile Dysfunction

IIEF: International Index of Erectile Function

IIEF-5: International Index of Erectile Function the abridged 5-item version

PAVED: Physical Activity to reduce Vascular Erectile Dysfunction

i-PAVED: information about Physical Activity to reduce Vascular ED

MRC: The Medical Research Council

SA-SH: Students' Attitudes towards Addressing Sexual Health

SA-SH-D: Danish version of Students' Attitudes towards Addressing Sexual Health

TFA: Theoretical Framework of Acceptability

RCT: Randomized Controlled Trials

CT: Controlled Trails

WHO: World Health Organization

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CHAPTER 1. INTRODUCTION

1.1. SETTING THE SCENE

For many men worldwide erectile dysfunction (ED) is a common problem (6). In most cases, ED is caused by cardiovascular risk factors (6). Physical inactivity, obesity, hypertension, metabolic syndrome and cardiovascular diseases are risk factor for vascular ED (6). There is increased recognition of the role of low-risk, low-cost, non-pharmacological and safe lifestyle interventions to lessen the burden of vascular ED (7). Regular physical activity can prevent and reduce vascular ED (7), and in this project the proposed intervention is called ‘Physical Activity to reduce Vascular Erectile Dysfunction’ (PAVED). Although ED is common for men with cardiovascular diseases (6) and physical activity is a core intervention in cardiac rehabilitation (8,9), cardiac health professionals rarely provide information about ED or its relation to physical activity (10,11). Because knowledge about PAVED is poor, the communicative component, information about PAVED (i-PAVED), includes professional-patient communication about ED, which contributes to making this intervention complex. In order to provide i-PAVED for men with cardiovascular risk factors for ED, it seems important to develop the complex intervention PAVED (11). This PhD project therefore addresses the development of PAVED.

1.2. DEVELOPMENT OF COMPLEX INTERVENTION

According to the Medical Research Council (MRC) complex interventions in health are identified by having a number of components that may act both dependently and independently, having “active components” that are important to define; being interventions that may be delivered at the individual, organisational or population level; and being targeted towards patients directly or indirectly through health professionals or health systems (12). Developing and evaluating complex interventions included the phases: Development, Feasibility and Piloting, Evaluation and Implementation (Figure 2) (12). The process of development of framework through to implementation of a complex intervention is characterized as a nonlinear or even a cyclical sequence. Improving the development of complex interventions can reduce research waste and enhance the likelihood of success and help design interventions that fit into practice (13). Focus in this project is narrowly on the development phase of PAVED (Figure 2).

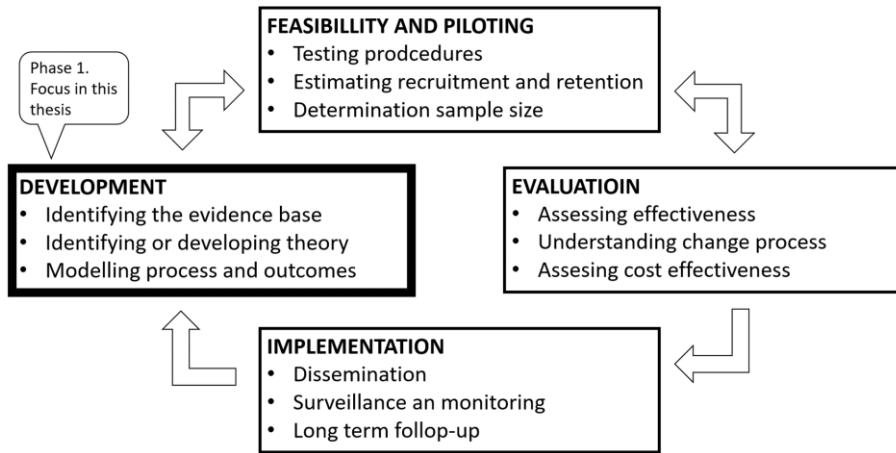


Figure 2. Developing complex interventions. Inspired by Craig et al. (14).

According to Craig et al. (14), the development phase consists of:

- Identifying existing evidence - systematic review of the relevant evidence should be conducted
- Identifying and developing theory - the rationale for a complex intervention, the changes that are expected, and how change is to be achieved should be developed or drawn from existing evidence and theory
- Modelling process and outcomes: modelling a complex intervention can provide important information about the design of the intervention.

As this project, concentrates on the initial phase of developing PAVED, a theoretical model enriching the MRC development phase by Bleijenbergh et al. (13) was an inspiration. The Adapted MRC Development Phase (Figure 3.) is a comprehensive approach that combines the elements of the MRC development phase with elements of other existing development models that can enhance the intervention design (13) and includes the following elements:

- problem identification and definition
- systematically identifying the evidence
- identifying or developing theory
- determine the needs
- examination of current practice and context
- modelling process and outcomes.

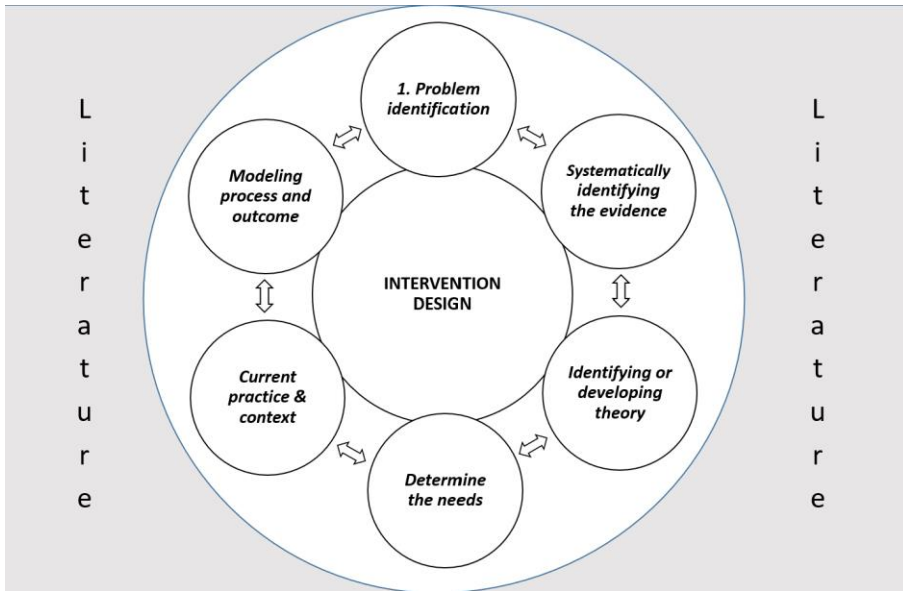


Figure 3. Adapted MRC Development phase. From Bleijenberg et al. (13)

Essential common principles are that the intervention should be evidence-based, have a solid theoretical rationale, match the individual needs, capacities and preferences of both recipients and providers, and fit into the context of routine practice (13). To optimize successful implementation of an intervention within its context, identifying the existing intervention practice is extremely valuable during the development process (13). This aims to explore the context in which the intervention will be implemented, by identifying barriers and facilitators regarding the proposed intervention among recipients and providers, to enhance the implementation of the intervention that closely fits current practice (13). A useful method is a logic model to synthesize and describe the complex pathways of the intervention (13).

This project focuses on the development of the intervention PAVED primarily regarding:

- identifying problems in the development and design of PAVED
- systematically identifying the evidence of PAVED
- identifying theory regarding PAVED
- identifying barriers in current practice
- determining the needs and preferences of potential future receivers of PAVED
- determining the capacity and needs of potential future providers.

By examining these elements, understanding of current practice will probably also be gained. Complex interventions in healthcare consist of several interacting components (12,14). PAVED comprises two main (hypothesized) active components: health professionals' communication and information, and men's performance of the needed level of physical activity and physiological mechanisms to reduce vascular ED (Figure 4).

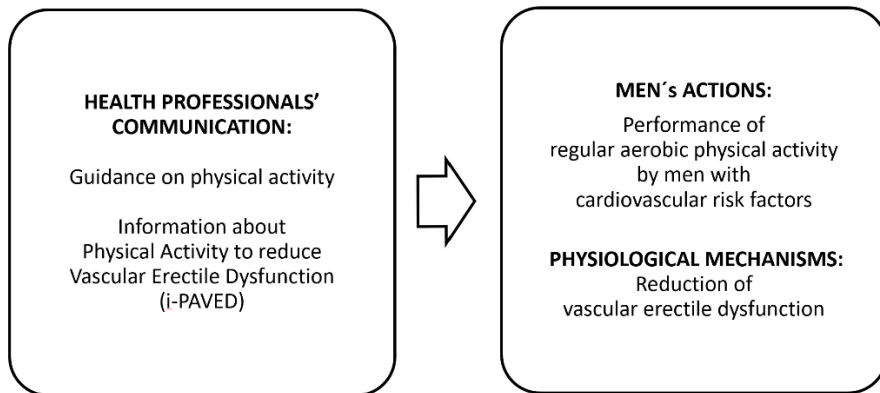


Figure 4. Components of the complex intervention: PAVED⁷.

The communicative components provided by health professionals and received by men consist of supervision and guidance for regular aerobic physical activity, and information about the fact that regular aerobic Physical Activity can reduce Vascular Erectile Dysfunction (i-PAVED), the latter being the main focus in this project. However, firstly, the theory and evidence regarding cardiovascular risk factors for ED and physiological mechanisms of physical activity are defined and identified.

1.2.1. TERMS USED AND DEFINED

In **Study I**, (1), the term 'improve erectile function' was used to emphasize a sexual health promotion and salutogenetic approach. In this thesis, the **Study I** term 'improve erectile function' corresponds to the term 'reduce vascular erectile dysfunction' (ED), since it seemed to be a clearer term when incorporating the ethology 'vascular' in the term used. When defining the ethology of ED in **Study I**, both the terms *arterial* ED and *vascular* ED were used (1). Arterial ED is included in the broader term *vascular* ED (6), which will be used in this thesis because of the association as well as the vocabulary correspondence of the terms '*vascular*' ED, '*vascular*' risk factors and *cardiovascular* disease, which hopefully can increase the intelligibility of the ethology and underlying mechanism of vascular ED.

⁷ PAVED: Physical Activity to reduce Vascular Erectile Dysfunction

For the same reasons, in this thesis and in the qualitative **Studies II** and **III**, term ‘cardiovascular secondary prevention and rehabilitation’ is used and chosen among terms across guidelines: ‘cardiac’ rehabilitation (9,15), ‘cardiovascular’ rehabilitation (16-18), cardiovascular disease prevention (17,19-21), cardiovascular secondary prevention (16), secondary prevention (18) and cardiovascular prevention and rehabilitation (17). When it comes to the specific municipal setting explored, the term ‘cardiac secondary prevention and rehabilitation’ is used, because it most appropriately represents the Danish term used for the service. However, in titles, linguistic wording or in consideration of sentence structure, shorter terms such as ‘cardiac rehabilitation’ or ‘cardiac health professionals’ are used to improve readability.

The World Health Organization (WHO) (22) emphasizes that cardiac prevention and rehabilitation, in addition to targeting the underlying causes of disease, aim to improve patients' physical, mental and social conditions, prevent complications and reduce mortality rates. This process includes the facilitation and delivery of prevention strategies (16). Cardiac rehabilitation programmes facilitate chronic cardiovascular disease care by specifically targeting patients' cardio-metabolic health and psychosocial well-being. The core components of contemporary cardiovascular prevention and rehabilitation programmes are intended to mitigate the atherosclerotic disease processes that drive cardiovascular disease progression and the related effects this has on psychosocial health. These components include individualized programmes of health behaviour and education interventions of physical activity and exercise, nutrition, psychological health, and smoking cessation (16). Secondary prevention also forms an integral part of effective cardiovascular prevention and rehabilitation. Likewise, defining the core competencies of professionals providing these core components helps align healthcare providers, educators, students, and administrators with defined expectations of knowledge and skills in providing cardiovascular prevention and rehabilitation services (16).

In **Studies I, II, III** and in this thesis, the term primarily used for physical activity is ‘physical activity’, which is defined as any bodily movement produced by skeletal muscles resulting in energy expenditure beyond resting expenditure (23,24). The energy expenditure can be measured in kilocalories, and physical activity in daily life can be categorized as occupational, sports, exercising, household or other activities (24). The current recommendation for physical activity in adults and older adults is ≥ 150 minutes of moderate intensity physical activity a week, and this is also the standard physical recommendation for patients with cardiac disease by the British Association for Cardiovascular Prevention and Rehabilitation (23). Exercise can be defined as a subset of physical activity that is planned, structured and repetitive, and has as a final or intermediate objective the improvement or maintenance of physical fitness (24). Therefore, in the review **Study I** and in this thesis, when it comes to the level, dose and modality of physical activity needed to reduce ED, the term ‘exercise’ or ‘exercise training’ is used. In the qualitative **Studies II** and **III** of men’s

perspectives, the term exercise is used in the quotes, as the men's phrasings were interpreted as planned physical activities.

In **Studies II and III** (2,3) and in this thesis, the terms 'men' and 'participants' were used and will be used to emphasize men's active role and an empowerment aspect of the intervention PAVED. The MRC uses the terms 'receivers' or 'recipients' of an intervention, contrasting the MRC term 'providers' of an intervention (12-14), while most scientific articles use the term 'patients'. Although the terms 'receivers', 'recipients' and 'patients' have connotations to a passive role, they will be used as a supplement in this thesis when applying, discussing and referring to the MRC theories and models and studies using these terms in order to demonstrate how the results of Studies II and III contribute to the development of PAVED.

Regarding terms for the 'providers' of PAVED, 'providers' of an intervention is an MRC term (12-14) that is used in this thesis when applying, discussing and referring to the MRC theories and models in order to demonstrate how the results of **Study V** contributes to the development of PAVED. Across the studies, a variety of terms for 'providers of PAVED' was used. In **Study I**: 'physiotherapists' (1), in **Studies II and III**: 'health professionals' (2,3), in **Study IV**: 'healthcare students' (4) and in **Study V**: 'Danish health professional students' (5). In this thesis, the students are termed 'Danish health professional students', 'future health professionals' and 'future providers of PAVED'.

1.3. IDENTIFYING THEORY AND EVIDENCE FOR PAVED

1.3.1. ERECTILE DYSFUNCTION

ED is defined as the inability to attain or maintain a penile erection of sufficient quality to permit satisfactory sexual activity (25), is prevalent in 18% in the general population (26) and represents the most common sexual dysfunction among men age 50-80 (27). Risk of ED increases during the adult lifespan with prevalence rates at ~60% at age 50-59 years, ~80% at age 60-69 years and ~90% in men > 70 years old (28-31). ED is a multidimensional, common male sexual dysfunction and a common concern for affected men and their partners (32) as it can greatly affect quality of life, and psychosocial and emotional well-being for both (33-35). To diagnose and quantify the severity of ED, the International Index of Erectile Function (IIEF score 6-30) (36) and the abridged 5-item version (IIEF-5 score 1-25) (37) are the most commonly used patient reported outcome measures, categorising ED as mild, moderate or severe. (See Introductions in **Study I**).

1.3.2. SEXUALITY AND SEXUAL HEALTH

According to the WHO, "Sexuality is a central aspect of being human throughout life and encompasses sex, gender identities and roles, sexual orientation, eroticism,

pleasure, intimacy and reproduction. Sexuality is experienced and expressed in thoughts, fantasies, desires, beliefs, attitudes, values, behaviours, practices, roles and relationships. While sexuality can include all of these dimensions, not all of them are always experienced or expressed. Sexuality is influenced by the interaction of biological, psychological, social, economic, political, cultural, ethical, legal, historical, religious and spiritual factors” (38). Sexuality is an important aspect of people’s physical and mental health, well-being and overall quality of life (39). Sexual health is a state of physical, emotional, mental and social well-being in relation to sexuality; it is not merely the absence of disease, dysfunction or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination and violence. For sexual health to be attained and maintained, the sexual rights of all persons must be respected, protected and fulfilled (38). The ability of men and women to achieve sexual health and well-being depends on their access to comprehensive, good-quality information about sex and sexuality, knowledge about the risks they may face and ability to access sexual healthcare living in an environment that affirms and promotes sexual health (38)

1.3.3. PENILE ERECTION PHYSIOLOGY

For a theoretical understanding of vascular ED, an explanation of the physiology of erection is useful. As normal erectile function involves multiple regulatory systems, including psychological, neurological, endocrine, vascular and cavernosal factors (40), ED can be induced by disruption of one or more of these systems (40). Sensory input from receptors in the skin, glans, urethra and corpora cavernosa travel via the dorsal nerve of the penis, and later the pudendal nerve, to S2–S4 nerve roots. Interaction with the thalamus and sensory cortex leads to parasympathetic activation and release of nitric oxide (NO) from the parasympathetic nerves and endothelial cells (28,40), resulting in increased cGMP, and ultimately vasodilation of the smooth muscle in the arteries supplying the penis, which expands penile volume by increased blood flow into the corpora cavernosa (41). This process is reversed by phosphodiesterase type 5 (PDE5) breaking down cGMP (41). Penile erection is a hemodynamic process involving increased arterial inflow and restricted venous outflow (1,42); therefore, ED can be an early warning sign of poor vascular function and vascular disorder (34). The artery size hypothesis is that given the smaller size of the penile vasculature (1–2 mm) compared to coronary vasculature (3–4 mm), ED is more likely to manifest earliest (28,34). Neuronal and endothelial NO mediates the vascular component of sexual arousal by causing engorgement of the corpora cavernosa tissue and subsequent erection of the penis (1,43). Erectile blood flow is regulated by constriction or relaxation of the smooth muscle cells of penile arterial vessels (43,44). Maximal erectile function results from relaxation of smooth muscle of the penile arterial vessels through activation of neuronal NO synthase and relaxation of smooth muscle in the corpora cavernosa through release of endothelial NO synthase (43). (See also introductions in Study I).

1.3.4. PATHOPHYSIOLOGICAL MECHANISM OF VASCULAR ED

Understanding the vascular type of ED is useful to theoretically understand how and why physical activity can make a change in vascular ED. ED may be classified as psychogenic, organic or mixed. Organic ED is most common, has a gradual onset, a constant disease course, and is associated with poor erections (45). Among organic ED, vascular ED is most prevalent (21,45,46). The common pathophysiologic bases for ED and cardiovascular diseases are believed to be consequences of chronic inflammation (45,47,48), endothelial dysfunction (45,48-51) and reduced NO production (43,52). Endothelial inflammation, which disrupts NO production, is a central determinant of vascular diseases, including ED (1,53,54), and seems to be the common pathological process causing ED (34). In most men with ED, poor lifestyle choices, a sedentary lifestyle and obesity causing endothelial dysfunction and vascular disease lead to insufficient NO production (43) (Figure 5).

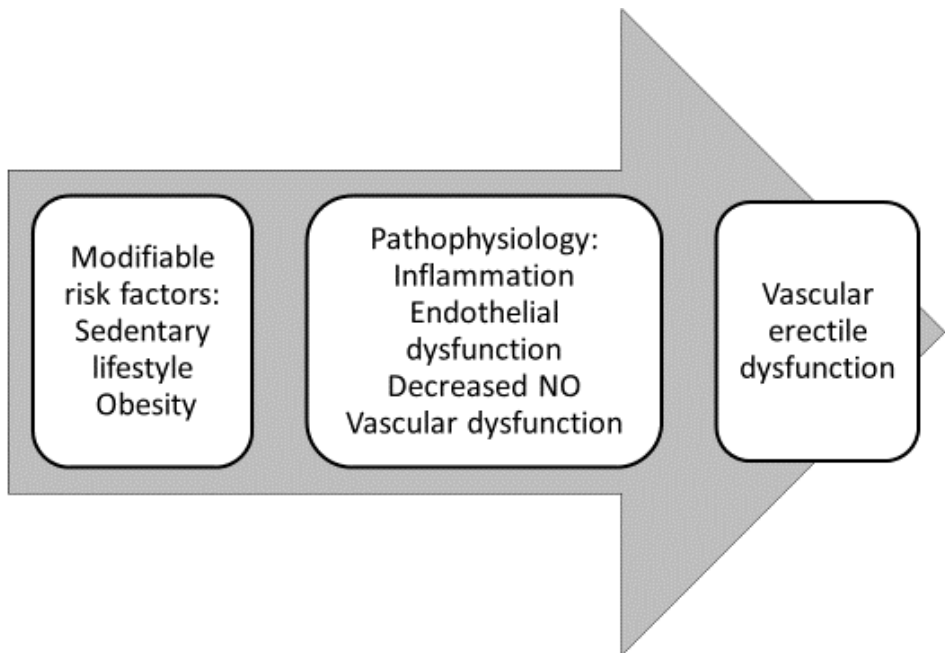


Figure 5. Relationship between modifiable risk factors and vascular ED

Reduced blood inflow may be due to atherosclerotic blockage or factors affecting endothelial function that prevent adequate vasodilation during sexual stimulation. (See introduction in Paper I). The main therapeutic strategy in clinical healthcare is to compensate for ED by using phosphodiesterase type 5 inhibitor (PDE5i) medications.

However, PDE5i only temporarily restore erectile function, and they have been found to be ineffective in a significant proportion of men with ED (55). Moreover, PDE5i medications do not appear to have any long-term impact on the underlying endothelial and vascular dysfunction and they do not have any curative effect on ED (55,56).

1.3.5. VASCULAR RISK FACTORS FOR ED

Common risk factors for atherosclerosis such as physical inactivity (57,58), obesity (34,58), hypertension (34,58), metabolic syndrome (57), and cardiovascular diseases are prevalent in men with ED (34). Vascular ED is linked to this complex of closely interrelated lifestyle choices and modifiable cardiovascular risk factors: physical inactivity (59), obesity (34,48,60), hypertension (32), metabolic syndrome (48,61,62) and cardiac diseases. Physical inactivity is a primary cause of most chronic diseases, including obesity, hypertension, metabolic syndrome, coronary heart disease, endothelial dysfunction, arterial dyslipidaemia and ED (41). Physical inactivity, obesity and hypertension are associated with imbalance in oxidative stress, leading to endothelial dysfunction (54). Sedentary men have a ten times higher incidence of erectile difficulties varying from mild to severe (63). Obesity is a state of chronic inflammation, oxidative stress, and insulin resistance. (64,65). Obesity, particularly central obesity is strongly associated with ED (64-66). ED is a frequent comorbidity of obesity, and globally a 70–95% higher risk of ED is reported in overweight or obese men compared to that of normal-weight subjects (48), and obese men have shown to be twice as likely to have ED as men in the normal weight range. Due to reviews and meta-analyses, hypertension is a risk factor for ED (33,67-70). The prevalence of hypertension and ED has steadily increased, and 30%-50% (71), more than 40% (72), and 71% (73) of men with ED concurrently share a diagnosis of hypertension. A systematic review and meta-analysis has found a positive association between ED and metabolic syndrome and between ED and all the components of metabolic syndrome (hypertension, hyperlipidaemia, obesity, insulin resistance) and revealed that men with metabolic syndrome had a higher overall risk of ED (70).

Modifiable lifestyle factors such as physical inactivity and obesity, are major contributors to the onset and development of both cardiovascular diseases and ED (33). There is consistent evidence that endothelial damage is intimately linked to ED. This manifestation seems to be associated with the appearance of cardiovascular diseases (54), and the association between ED and subclinical cardiovascular diseases is demonstrated in a meta-analysis (74). ED is reported in up to 81% (75) and 93% of men (over 65 years) with cardiovascular diseases. ED has been called “penile angina” because it can be predictive of future cardiovascular diseases (1,7), and ED is frequently caused by cardiovascular risk factors diseases (1,42,44). ED and cardiovascular diseases should be regarded as two different manifestations of the same systemic disorder (47), as they are closely linked and consequences of endothelial dysfunction (54,76) – the latter causing restrictions in blood flow (76) and being a leading cause of death in men (45). Vascular ED is a strong indicator of premature

mortality (33,77,78). A meta-analysis of prospective cohort studies concludes that ED significantly increases the risk of cardiovascular diseases and all-cause mortality, and the increase is probably independent of conventional ED and risk of cardiovascular diseases (51). (See introduction to Study I, and Figure 6).

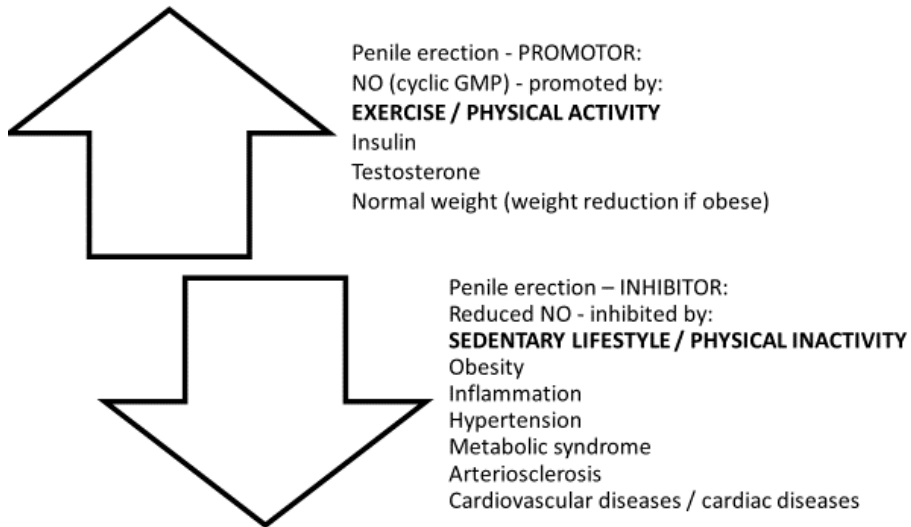


Figure 6. Erectile function and physical activity

1.4. RATIONALE AND EXISTING EVIDENCE OF PAVED

Already in 450 BC, Hippocrates thought that physical activity was preventive of chronic disease and that *walking is man's best medicine* (79). Physical activity is associated with prevention of obesity, hypertension, metabolic syndrome, and cardiovascular disease (80). Since 2000, epidemiology studies, reviews and meta-analysis have documented evidence of regular moderate and high levels of physical activity in preventing the development of vascular ED (63-65,81-85). This is also the case for men under 40 (86,87). Moderate physical activity reduces the risk of ED by 66%, high physical activity reduces the risk by 80% (52,88), and for every 30 minute daily increase in moderate-to-high physical activity, men have a 43% reduced odds of having ED (77). Physical activity has a dose-dependent association with ED because the risk of ED decreases with greater physical activity (89). The protective effect of PA also applies to men with obesity, hypertension and metabolic syndrome (43,82,90,91). In the influential publication 'Exercise as medicine' (92), ED was not among the 26 included chronic diseases. Physical activity improves endothelial function and NO production (42,44,52-54,93), and previous reviews have found that there is strong evidence that frequent physical activity significantly reduces ED (7,56,71). In summary, the key rationale for PAVED could be identified in existing

evidence and theory, and men's actions in the form of physical activity can be defined as an active and effective component of PAVED. In relation to the development of the components of health professionals' guidance of physical activity and men's aerobic physical activity (Figure 4), important knowledge on *how* a change of vascular ED can be achieved was lacking because the level (i.e., modalities, duration, intensity and frequency) of physical activity was insufficiently described. According to Bleijenberg (13), the goal is to develop an effective intervention and identify what works, what works for whom, and what determinants are modifiable within the causal pathway. An identified problem regarding development of the intervention PAVED was a lack of recommendations for physical activity-induced reduction of ED (PAVED). In-depth knowledge was needed in regard to the specific level – modality, duration, intensity and frequency – of physical activity needed to reduce vascular ED in men characterized by physical inactivity, obesity, hypertension, metabolic syndrome and/or manifest cardiovascular disease. An identification of the existing evidence of clinical intervention studies could provide this knowledge or indicate the need for future research in this field.

1.5. IDENTIFYING POTENTIAL BARRIERS IN CURRENT PRACTICE

According to Bleijenberg (13), potential barriers among recipients and providers are identified to enhance how PAVED could fit current practice. Regarding the communicative component of PAVED (Figure 4), which consists of supervision and guidance for regular aerobic physical activity as well as i-PAVED, the former is currently a core component of health professionals' interventions in cardiac secondary prevention and rehabilitation programmes (8,9,18). However, when it comes to i-PAVED, less is practiced and less was known since sexuality is seldom addressed in practice during cardiac rehabilitation (75,94,95). ED often remains overlooked, under-diagnosed and under-treated by health professionals (50,75,96-99), who rarely discuss ED and sexual health with men (10,100,101). Health professionals often underestimate the prevalence of decreased sexual health and thus neglect to address sexual health in their interventions regarding prevention, treatment and rehabilitation (102,103), especially when the patients are older adults (104-106). A majority of the health professionals reported in a survey that they do not offer sufficient care and rehabilitation regarding sexual health, and most of them never initiate a conversation about sexual health with patients (95). Common barriers are socio-cultural norms (10,105), priority (10,105,107), time (10,105,107) and organisational support (107,108). Negative experiences of professional inadequacy and lack of institutional policy are shown to hinder health professionals in integrating sexual health and intimacy issues into their professional capacity (104,107,109,110). Additionally, there are barriers such as professionals' embarrassment (107,109-112) and lack of education (10,105,107,109,110,113-115), knowledge (10,107-109,112-114), training (10,105,114,116), expertise and communication skills (105,109,112), and the view that sexual health is not part of their professional responsibility (10,107,111,112,114). Health professionals rarely seem prepared to address and discuss sexual issues with

their patients (10,104,107,111). Common patient-related barriers for health professionals' address of sexuality and ED are their fear of offending patients (112) or increasing patients' discomfort (94), their belief that patients would feel embarrassed or offended if sexual health is discussed, and that it is too private to discuss (94,107). Additionally, there are the barriers of health professionals' impression of patients' lack of readiness and initiative to bring up the subject of sexual health (94,117). Those barriers are also identified among health professionals working with men with cardiovascular diseases (94,112,117).

1.5. POTENTIAL RECEIVERS OF PAVED

Receivers' perspectives should be taken into account in the earliest stages of the design phase (13). Potential receivers of PAVED are men with vascular risk factors for ED (Figure 7).

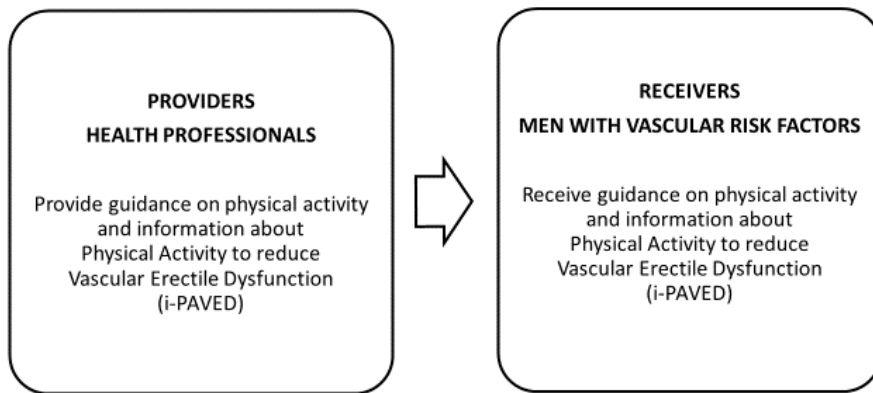


Figure 7. Providers and receivers of PAVED

Men with cardiovascular diseases are among those having several risk factors for vascular ED (51) (Figure 6). Although Danish guidelines recommend health professionals to address sexuality (118,119), this rarely happens in daily cardiac practice (10,103). ED can be a sensitive topic and is underreported by men (120,121), so if health professionals do not ask about it, men do not tell about it (97,122). Men with cardiovascular diseases lack knowledge about risk factors for vascular ED, and studies have proposed that it could be helpful for them to discuss ED with health professionals (46). Acceptability of the intervention must be studied (12), and understanding of men's acceptance of health professionals' address of sexuality and ED is unclear. Thus, an identified possible problem for development and prospective provision of PAVED was whether health professionals' address of ED and i-PAVED can be perceived acceptable for men - the potential receivers of PAVED. Identifying the current problem in a specific context can provide insights into the current gaps

(13). It was unclear whether Danish men attending municipal cardiac secondary prevention and rehabilitation programmes can accept health professionals' address of sexuality, ED and i-PAVED. Development of successful interventions depend on the receivers' acceptance (123). At the same time, from receivers' perspective, the content, context and quality of communication may all have implications for acceptability (123). Therefore, in the developing phase of the complex healthcare intervention PAVED it was important to explore men's accept of health professionals' address of sexuality, ED and i-PAVED.

Due to health professionals' limited communication about i-PAVED, guidelines and advice for their communication with men were required (11,124). Guidance of regular aerobic physical activity is recommended in guidelines for cardiovascular secondary prevention and rehabilitation (8,18,20,22), which currently is multi-disciplinary and combines physical activity with a healthy lifestyle, management of cardiovascular risk factors and enhancement of psychosocial wellbeing (20). Patient educational programmes promoting physical activity are recommended to include information about the impact of modifiable risk factors on ED (125,126), and such information is hypothesized to be motivating for men to improve their physical activity level (127). Health professionals' communication about ED is recommended in international guidelines (10,20,22,128) as well as Danish guidelines for cardiovascular secondary prevention and rehabilitation (8,119,129). According to guidelines on the management of ED, modifications in lifestyle can reduce the risk of ED and lifestyle changes and risk-factor modification should accompany any specific pharmacotherapy or psychological therapy (level of evidence 1b, recommendation A) (130). Guidelines for managing of ED for men with cardiovascular diseases recommend physical activity to reduce ED (Level 1, Grade A) (96,130,131).

However, men's knowledge about the link between a sedentary lifestyle and ED is poor (126,132), which was an identified problem showing the need for developing health professionals' communication about i-PAVED. The perceptions of recipients regarding the problem are highly important, and a thorough understanding of their needs, perceptions and preferences is a fundamental element that needs to be incorporated in the development process (13). The perspectives of men in municipal cardiac preventive and rehabilitative programmes concerning i-PAVED have not previously been explored. A goal is to develop an intervention that can fulfil the needs of its receivers. Thus, investigating the care needs and perceptions of the recipients is crucial (13), and an elucidation of men's perspectives in relation to health professionals' communication about i-PAVED could provide this insight in order to develop a feasible, acceptable and effective intervention for this population in the future cardiovascular secondary prevention and rehabilitation programmes.

1.6. POTENTIAL FUTURE PROVIDERS OF PAVED

In developing a complex intervention, a goal is to develop an effective solution that addresses the clinical problem, and can be replicated by future providing health professionals (13); therefore, it is essential to investigate the potential providers' capacities with regard to the proposed intervention (13). Future providers of PAVED are health professionals (nurses, physiotherapists and occupational therapists) working with men with vascular risk factors – the receivers of PAVED (Figure 7). In Denmark, the prevalence of men with vascular risk factors such as physical inactivity, obesity and related diseases is increasing and therefore an increasing public health issue (133). There is an increasing prevalence of men with obesity and hypertension in need of healthcare (134), which makes the provision of PAVED and the communicative component i-PAVED (Figure 4) relevant in various healthcare contexts targeting and including men with vascular risk factors. The preventive effect of physical activity on ED emphasizes the relevance of providing PAVED on a large scale of primary, secondary and tertiary prevention, and health promotion interventions for the general population.

According to the identified multifactorial barriers for health professionals in addressing sexuality and ED, a possible problem for the development and prospective provision of PAVED can be identified as whether potential future health professionals have the competence and capacity to provide the communicative component i-PAVED (Figure 4). Provision of i-PAVED requires health professionals to inform and communicate about ED, which is in line with health professionals being recommended to address sexual health during preventive and rehabilitative interventions (103,135). Consequently, health professionals should be confident and supportive in order to appropriately address sexual health (136). To be able to meet patients' needs, health professional students (nursing, occupational therapist and physiotherapist) must be prepared to address sexual health in their future professional preventive and rehabilitative interventions (135,137).

Danish health professional students' attitudes towards addressing sexual health have only been investigated in a small controlled intervention study, which indicated that the students perceive themselves as having limited ability in communication, low capacity, competence and educational level in the field of sexual health (138). However, other studies found that nursing, occupational therapy and physiotherapy students have positive attitudes towards working with sexual health, despite their lack of knowledge and practice (135,139-141). However, the health professional students have a high level of discomfort concerning communicating about sexual issues, and they report their sexual health education to be insufficient and express a need for additional education within this field (135,139-141).

In developing of a complex intervention, the effectiveness of the intervention is determined by the extent to which the capacities of future providers are taken into

account (13). Studies have shown that health professional students' attitudes may affect how they succeed in addressing the sexual health needs of their future patients (135). However, the question of whether the students have the capacity to take an active role in providing i-PAVED in clinical health promotion, prevention and rehabilitation, presuming that they have sufficient knowledge about sexual health, needed further research. Thus, there was a need for knowledge regarding Danish health professional (nursing, occupational therapy, physiotherapy) students' attitudes towards addressing sexual health. To understand Danish health professional students' address of and communication about sexual health in their future professional interventions, it was essential to investigate nursing, occupational therapy and physiotherapy students' current attitudes, perceived capacity and competence regarding address of sexual health. In the development phase, surveys can be useful to investigate providers' perspectives (13).

In order to investigate health professional students' attitudes towards addressing sexual health, an appropriate questionnaire was required. A problem identified was the lack of literature on Danish questionnaires measuring attitudes towards working with and communicating about sexual health. However, there was a relevant, valid and reliable Swedish questionnaire, Students' Attitudes towards Addressing Sexual Health (SA-SH) (142). There are cultural similarities, differences and language differences between the Nordic countries; therefore, a translation and psychometric test of the translated questionnaire in a Danish context was necessary to be able to use the SA-SH in a Danish survey of health professional students' attitudes towards addressing sexual health in their future professional work.

1.7. SUMMARY

In summary, in relation to developing the complex intervention, PAVED, existing evidence and physiological rationale for PAVED were identifiable. To develop the physical activity component, it was considered relevant to look into the evidence for the needed level of PAVED and issues related to sexual health because ED can be identified as sensitive and a communication challenge in healthcare. In relation to the communicative component, it was considered relevant to shed light on potential receivers' needs, acceptance and perspectives regarding health professionals' address of and communication about i-PAVED as well as potential future providers' capacity to provide the communicative component of PAVED. There was a need for knowledge about the level of PAVED to successfully reduce ED for men with risk factors for vascular ED. Regarding, the component i-PAVED, firstly, there was a need to understand the acceptance and perspectives among potential receivers of PAVED – men with cardiovascular diseases – in terms of health professionals' address of and communication about i-PAVED. Secondly, there was a need for knowledge about the dissemination capacity of potential future providers of PAVED and i-PAVED (health professional students) regarding their attitudes towards addressing sexual health. As

a prerequisite to produce that, a translation of the SA-SH into Danish and a psychometric test of the translated questionnaire was needed.

CHAPTER 2. GENERAL AND SPECIFIC AIM OF THE PROJECT

2.1. OVERALL AIM

The overall aim of this PhD project was to develop the complex intervention Physical Activity to reduce Vascular ED (PAVED) for men with vascular risk factors for ED using evidence-based approaches and focusing on the following:

- 1) Evidence on the physical activity level needed to reduce vascular ED.
- 2) Acceptance and perspectives among men with cardiac diseases on health professionals' address of and communication about i-PAVED.
- 3) Future health professional providers' capacity, attitudes, readiness and competence to address sexual health.

The PhD project and this thesis are based on the following five studies with their respective aims.

2.2. STUDY-SPECIFIC AIMS

- I. **Study I:** The aim of this study was to provide recommendations on physical activity level needed to decrease vascular ED for men with physical inactivity, obesity, hypertension, metabolic syndrome, and/or cardiovascular diseases (1).
- II. **Study II:** The aim of this study was to explore how acceptance of cardiac health professionals' address of sexuality, ED and i-PAVED can be identified in men's narratives (2).
- III. **Study III:** The aim of this study was to clarify men's perspectives on cardiac health professionals' communication about physical activity to reduce vascular erectile dysfunction (3).
- IV. **Study IV:** The aim of this study was to translate and psychometrically test the Danish version of the questionnaire Students' Attitudes towards Addressing Sexual Health (SA-SH) (4).
- V. **Study V:** the aim of this study was to investigate Danish health professional students' attitudes towards addressing sexual health in their future professional practice and to explore differences in students' perceived competence and preparedness depending on educational programme (5).

CHAPTER 3. METHODS AND RESULTS

3.1. DESIGN

The research design of the PhD project was the development of the complex intervention: Physical Activity to reduce Vascular Erectile Dysfunction (PAVED), using the MRC Framework Developing and Evaluating Complex Interventions as a framework for the project (12). In the development phase, a reciprocal relation between the elements exists (12,13); thus, in developing the complex intervention, PAVED, a recommended iterative approach was applied. In this reflective process, a literature review as well as quantitative and qualitative research to enhance the design of PAVED were used. The Adapted MRC Development phase (Figure 3) by Bleijenberg et al. (13) inspired the specific aims that defined the design, methodology and methods. Both quantitative and qualitative methodologies and data were used correspondingly to answer the specific aims of the studies (for an overview of the studies see Figure 1 and Table 1).

Study I was a systematic review (1). **Studies II and III** were qualitative individual interview studies (2,3). **Study IV** was a psychometric study (4) and a request for **Study V**, which was a national survey (5).

Methods and results are presented in the following order: **Study I**: Identifying evidence for the level of PAVED; **Studies II and III**: perspectives of men with cardiovascular diseases – potential receivers of PAVED; **Studies IV and V**: capacities of potential future providers of PAVED. For an overview of the studies, see Figure 1 and Table 1. For readability, the aim of the studies is presented in relation the specific studies.

3.2. EVIDENCE OF REQUIRED LEVEL

The aim of the study was to provide recommendations of physical activity level needed to reduce vascular ED for men with physical inactivity, obesity, hypertension, metabolic syndrome and/or manifest cardiovascular diseases.

3.2.1. METHODS - STUDY I

3.2.1.1. SEARCH STRATEGY

The systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (143) and was based on PICO (143) and “Building Block Search” (144). To identify eligible studies, selected databases were systematically searched. In co-operation with an experienced research information specialist, the search was carried out by using the search terms ‘physical

activity', 'erectile dysfunction' and additional synonymous terms (see Paper I). An initial screening of titles and abstracts identifying potentially relevant studies was performed using Covidence (145).

3.2.1.2. STUDY SELECTION AND DATA SELECTION

The formulated inclusion and exclusion criteria ensured inclusion of groups with vascular risk factors for ED and exclusion of non-vascular risk factors for ED. The studies included in the review meet the following inclusion criteria:

- 1) Study design: randomized controlled trials (RCTs) or controlled trails (CTs)
- 2) Study population: men at least 18 years old with arterial ED and men characterized by physical inactivity, obesity, hypertension, metabolic syndrome, and/or manifest cardiovascular diseases
- 3) Study intervention: any exercise protocol involving PA to decrease ED
- 4) Baseline and follow-up measurements: ED measured using the IIEF score (maximum 30 points) or IIEF-5 score (maximum 25 points) and exercises measured by modality, duration, intensity and frequency
- 5) Publication: studies should be included in full-text articles and originally published in peer-reviewed journals from 2006 through 2016. Exclusion criteria were studies including population groups with ED caused by neurologic disorders, hormone disorders, psychiatric disorders, cancers, diabetes mellitus, HIV, liver or kidney diseases, major surgery, radiotherapy, or side effects of medications.

Based on these criteria, all identified studies were subsequently screened. The study selection process was documented in a flowchart (see Paper 1, Figure 1). Key characteristics of the included studies were registered in Paper I, Table 1. Evaluated risk of bias in the selected studies is presented in Paper I, Table 2 and Figure 2.

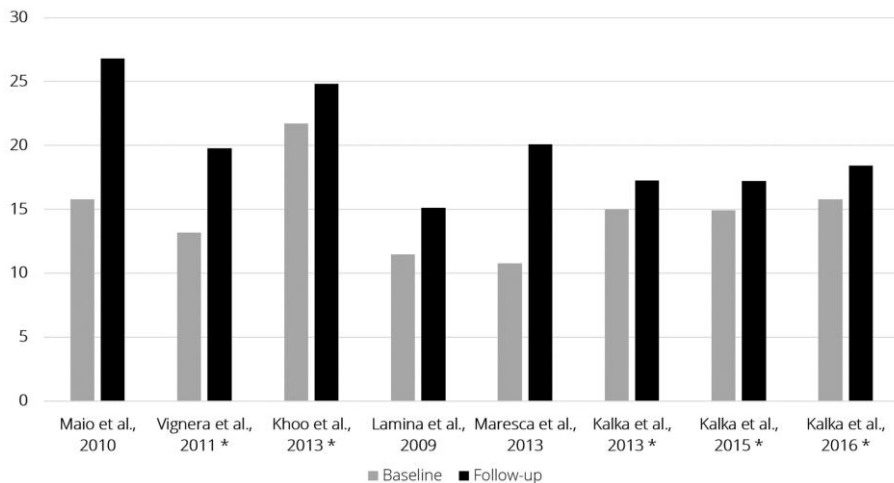
Studies reporting the IIEF or IIEF-5 score in the intervention and control groups at baseline and in follow-up were extracted in relation to predefined criteria including mean IIEF or IIEF-5 scores, ED category scores, intervention physical activity level and whether supervised or unsupervised. Reduction of ED analysed by calculating the relative change is provided in Paper I, Table 3. Illustration of reduction of ED in the intervention groups, is provided in Paper I, Figure 3. Level of physical activity modalities, intensity, duration, frequency, weekly dose, period and delivery (supervision) of the programme for the intervention groups is provided in Paper I, table 4. An illustration of the relative reduction in ED for the intervention and the control groups is provided in Paper I, Figure 4.

3.2.2. RESULTS – STUDY I

An overview of the ten included studies is provided in Paper I, Table 1, which shows that each of the five study groups: physical inactivity, obesity, hypertension, metabolic syndrome and/or manifest cardiovascular diseases was presented by one to four studies. The estimated moderate risk of bias appeared in several ways; mainly due to impossible blinding of participants and staff, unclear blinding of outcome evaluators and risk of selection bias in nearly half of the studies.

3.2.1.3 REDUCTION OF ED BY PHYSICAL ACTIVITY

An overview of the intervention physical activity-related reduction of ED. The ED scores are presented at baseline and follow-up for the intervention and control groups and the relative reduction of ED is presented.



*Figure 8. IIEF⁸ scores at baseline and follow-up for intervention. *The IIEF-5 measurements have been scaled to IIEF range.*

The mean IIEF scores at baseline and follow-up for the intervention groups are illustrated (see Figure 8, and Paper 1, Figure 3), and demonstrates a reduction in ED for all the intervention groups. An illustration of the relative reduction of ED is provided in Paper I, Figure 4, and demonstrates that the intervention groups achieved a reduction of ED from 14% to 86%, compared to the control groups for which the change varied from a worsening of 5% to an improvement of 59% (1).

⁸ IIEF: International Index of Erectile Function.

3.2.1.4. LEVEL OF PHYSICAL ACTIVITY

An overview of the physical activity level for the intervention programmes in the included studies in relation to IIEF / ED scores and relative reduction of ED is provided in Paper I, Table 3. Details of the physical activity level for intervention programmes are provided in Paper I, Table 4, presenting the variation in level. In all 10 studies, the training *modality* was *aerobe* and the *intensity* of the aerobic training was *moderate* and supplemented by intervals of *high intensity* or with *resistance* training. In almost all programmes, individual supervision of participants was included. The mean *duration* of each training session was *40 minutes* (20-60 minutes), the mean weekly *frequency* was *four sessions a week*, the mean weekly physical activity level was *157 minutes* (120-300 minutes) and the mean training *period* was six months (2 months – 2years) (1).

3.3. MEN'S PERSPECTIVES

3.3.1. METHODS – STUDIES II AND III

Studies II and III were qualitative individual interviews following the guidelines of Consolidated Criteria for Reporting Qualitative Research (COREQ) (146). They share the same data corpus (147) but use different data sets, as the approach in **Study II** was a concept-driven content analysis (2) whereas **Study III** made use of a data-driven analysis (3). Thus, two data sets were created, using a deductive respectively inductive approach in combination with the specific aim and research question of each study. **Study II:** The aim was to explore how acceptance of cardiac health professionals' address of sexuality, ED and i-PAVED can be identified in men's narratives. **Study III:** The aim was to clarify men's perspectives on cardiac health professionals' communication about PAVED.

3.3.1.1. PARTICIPANTS

In both **Studies II and III**, men attending municipal cardiac secondary prevention and rehabilitation in Denmark were eligible for interview. In collaboration with the staff, the researcher gave potential participants verbal and written information. The mean age of the 20 participating men was 61 (range 47-78 years). The men reported having several vascular risk factors and ED. Their other characteristics are provided in Paper II, Table 2 and Paper III, Table 2.

3.3.1.2. DATA COLLECTION

In **Studies II and III**, the interviews were conducted from a semi-structured interview guide with open questions based on the specific aim of the project and research in the fields (148).

Study II (2): The interview themes focused on the participants' experiences, attitudes, feelings, preferences and boundaries in relation to health professionals addressing issues related to cardiovascular diseases, sexuality, ED and i-PAVED. The interview guide is provided in Paper II, Table 3. **Study III (3):** The interview themes focused on the participants' perspectives, needs, preferences and beliefs related to health professionals' communication about ED and i-PAVED. The interview guide is provided in Paper III, Table 3.

The interviews in **Studies II and III** took place either at the municipal cardiac secondary prevention or rehabilitation localities, or in the participants' private homes. The first author of Paper II and Paper III conducted all the interviews. All participants were interviewed once and data collection continued until meaning saturation for the research questions of both studies was reached (149). The first author of Paper II and Paper III transcribed all interviews verbatim.

3.3.1.3 ANALYSIS

Study II was inspired by a concept-driven approach (150), where the Theoretical Framework of Acceptability (TFA) (123) (Figure 9) was used as a conceptual frame, and the interviews were analysed through a qualitative content analysis (150,151).

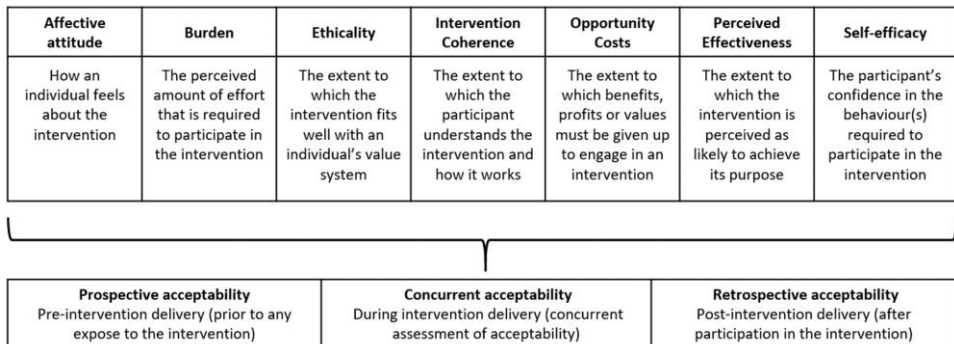


Figure 9. The components of the 'Theoretical Framework of Acceptability' (123)

The transcribed material underwent a first-step concept-driven coding (150) drawing upon the TFA. Thus, the text was coded into categories structured in advance and derived from the three temporal perspectives of 'prospective', 'concurrent' and 'retrospective' acceptability and the seven components of 'Affective Attitude', 'Burden', 'Ethicality', 'Intervention Coherence', 'Opportunity Costs', 'Perceived Effectiveness' and 'Self-efficacy' in the TFA (123), which is defined in Figure 9. In the next, data-driven step, items were analysed separately using qualitative, thematic content analysis (150-152).

In **Study III**, an inductive, data-driven thematic analysis was performed, in order to search for meaningful patterns (themes) across the interviews (147). Transcription of the verbal data was the first step of interpretation, followed by initial code generation (147). Then, more structured and analytically, meaningful themes were identified, named, interpreted and discussed including other research and theories (147). In **Studies II and III**, the data were processed in NVivo 2 (NVivo qualitative data analysis software; QSR International Pty Ltd. Version 12, 2018) (153).

3.3.2. ETHICS – STUDIES II AND III

In **Studies II and III**, ethical considerations followed the directions of the Helsinki Declaration (154). The study was reported to and approved by the UCL University College Data Protection Agency (Journal Number: UCL-2015-57-0016-040).

3.3.3. RESULTS – STUDIES II AND III

The main results of **Studies II and III** are presented below. For exemplifying quotes and elaborated analyses, see the results sections of Paper II and Paper III.

Study II: Men's acceptance of health professionals addressing sexuality, ED and i-PAVED was identified in six out of seven components of the TFA, as no narratives were identified in relation to the component of 'opportunity costs'. An overview of themes, subthemes and examples of identified narratives is provided in Table 2 (and in Paper II, Table 3):

Table 2. Themes, subthemes and examples of identified narratives

Theme	Subtheme	Examples of identified narratives	Temporal perspective	TFA Component
Interpreted	Interpreted	Coded	Coding category	Coding category
Expression of interest	Motivation and openness	"After all, it is off limits. No information [about sexuality] has been given to me" (6).	Retrospective	Affective attitude
		"I think it is allowed to ask that – it is very natural" (13).	Retrospective	
	Shyness	"Well, that's just something I find it really difficult to talk about." (11)	Retrospective	

	Speechlessness and frustration	<i>"It's a little bit strange, so we have 2019 and sexuality is still a taboo, and they (HPs) can't talk about it. I think it is strange, it still puzzles me" (12).</i>	Retrospective	
		<i>"If you can talk so much about smoking and wrong food and unsaturated fatty acids, why the hell should we not be able to talk about these things (i-PAVED)?" (5).</i>	Prospective	
Not bothersome, yet a potentially emotional effort	Not bothersome or offensive	<i>"It was not bothersome ... I was not offended by it" (9).</i>	Retrospective	Burden
		<i>"There is nothing compromising about that" (15).</i>	Prospective	
	Individual sessions	<i>"An individual consultation to get a deeper talk ... It could be an HP who is actually trained to handle those conversations; then I think it would be okay" (5).</i>	Prospective	
In harmony with men's attitudes and values	Educated and competent HPs	<i>"But I think you [HPs] could have talked about it [sexuality and ED] a little more dignified instead of just casually: "Well, just try these [PDE5-i]". A doctor and a nurse should be able to do that. I find it strange that it is not part of basic education, both for doctors and nurses and others" (3).</i>	Retrospective	Ethicality
	Caring for integrity	<i>"But as I said, there may be some who find it more difficult than others to talk about such things. I can only</i>	Prospective	

PHYSICAL ACTIVITY TO REDUCE VASCULAR ERECTILE DYSFUNCTION

		<i>... speak for myself. Maybe some will be offended that they [HPs] ask questions about their sex life. It would not bother me, but some might think: it is none of your business" (7).</i>		
Understandable and meaningful	Vascular ED was understandable	<i>"All of it makes a lot of sense; that it (penis) did not want to get up and that it has lasted so long. I have had ED for 5-10 years. I have had heart problems for a long time. So, it has not developed in 5 minutes – the arteriosclerosis – it has probably been there all 10 years. It is certainly relevant. You get so much information and much of it is about heart problems, and there is nothing about that [ED] in those leaflets. It could have been nice if she [the nurse] had said that [atherosclerosis] could be the reason why you can't get an erection, that atherosclerosis was all over in the body, instead of just right there in the heart" (6).</i>	Concurrent Retrospective Prospective	Intervention coherence
	i-PAVED was meaningful	<i>"No, I did not know; well, it actually makes sense. Of course, if you have those blood circulation problems, they also appear 'down there' [in the penile swelling bodies]. Of course, they do – in that area of the body. That exercise can help alleviate those inconveniences. It makes good sense, then. That</i>	Concurrent	

		<i>is common sense. Yes, it makes perfect sense" (12).</i>		
Better understanding	Better understanding of my ED	<i>"It is important to know how it all works, and especially if you go around speculating about a whole lot of things [ED]. Then I could have avoided that, if I had known something about it; therefore, it is necessary and important to get information on all aspects of life – also this [sexuality and ED]" (15).</i>	Retrospective Prospective	Perceived effective-ness
	My partner could understand me better	<i>"Yes, but I think so, because my wife also tries to guess what is the cause [of ED], and I also think it would be nice to "lay some ghosts to rest; that it's not her fault, so I think that would be completely relevant. Because I also know that my wife is just as affected as I have been and still am, and I have felt sorry for my wife. So, in that way I think - it would be extremely relevant" (3).</i>	Retrospective Prospective	
Self-care and motivation	Self-care to prevent or reduce ED	<i>"It is not enough to tell us about the [ED] problems, and then stop there. What most people would like to hear is if you can do something about it. Otherwise, men collect dust; men wrap it up and hide it. Dialogue is important, because then men come to think of something that they can do themselves. You can talk about it [ED] or describe it [ED] so men can see, though I am on my way there,</i>	Prospective	Self-efficacy

		<i>what can I do to turn it around before it's too late. Leaflets should be available, like dietary guidance – a potency guide, what can you do about it yourself". (10)</i>		
	A motivation for improving physical activity	<i>"Yes, I think so, of course - just to be reminded that it [physical activity] has an effect ... down there [in the penile swelling bodies] also, when ... yes: 'well it might be a good idea if I go for a run'. Because there are many, it may be that they are told that you live a year or two longer, but that is out in the future" (7).</i>	Prospective	

The analysis revealed men's experience that cardiac health professionals either had not addressed or only briefly addressed sexuality and ED. The men seemed to be *prospectively* interested, motivated and open-minded in relation to health professionals addressing these issues, and they did not seem to consider the topic to be annoying, bothersome or offensive. The address of sensitive issues such as ED could be a potentially emotional effort when sexual issues are addressed in group sessions. Men who were perceived as shy underlined the importance of the possibility to keep their head down, and for men in general individual sessions with health professionals trained in communication in the field of sexology could fulfil an unmet need of sexual counselling. *Retrospectively*, men had feelings of frustration when health professionals did not address relevant issues in relation to sexuality and ED. Health professionals addressing sexuality, ED and i-PAVED was in harmony with men's attitudes and values, and they cared for their own and other men's integrity and boundaries. The men had not received any information about links between cardiovascular diseases and vascular ED or about i-PAVED; however, these links were found to be understandable, meaningful and relevant. Health professionals' potential address of these links appeared to be useful for men and their partners, both in understanding vascular ED and in improving communication in couples. *Prospectively*, the men accepted that health professionals provided information, dialogue, self-care advice and written material about treatment options and self-care to prevent or reduce ED. The men found that the address of i-PAVED might be a potential facilitator for their self-efficacy by increasing their motivation to be more

physically active and thereby reduce vascular ED and improve cardiovascular rehabilitation. A prerequisite for men's acceptance of health professionals' address of sexuality, ED and i-PAVED was that health professionals are educated, competent and trained in communication in the field of sexology (2).

Study III: According to the men, ED was perceived as a major problem and they requested help to self-help by health professionals competent in the field. An overview of these themes and related subthemes are presented in Table 3.

Table 3 Overview of themes and subthemes regarding HPs' communication

Health professionals' communication concerning i-PAVED⁹ – perspectives of men in cardiac secondary prevention and rehabilitation			
Themes	Erectile dysfunction – a major problem	Help to self-help	Competent health professionals
Subthemes	<ul style="list-style-type: none"> • Diminishes masculinity • Affects relationship • Tabooed by health professionals 	<ul style="list-style-type: none"> • Content of communication • Context of communication 	<ul style="list-style-type: none"> • Permissible communication • Trust, safety and competence

In the men's perspective, ED was a taboo topic for health professionals, but communication about ED was needed because the men experienced ED as a major problem diminishing their masculinity and leading to unsolved, uncertain, inexplicable mystery that negatively affected their relationships. In relation to the content and context of health professionals' communication, the men only wanted general information in group sessions about sexuality, (vascular) risk factors for ED, i-PAVED and intimacy, which could provide them with knowledge and understanding of ED. Health professionals should give permission to address these sensitive issues as well as general information regarding self-help on how to prevent, reduce, compensate for and cope with ED. More specific and person-centered counselling was considered better suited in individual sessions, either alone or together with their partner. Available written material regarding ED and i-PAVED was also believed to be beneficial. Health professionals should be able to communicate about sexuality, ED and i-PAVED in an open, empathetic, trustful and emotionally safe way and be knowledgeable, educated and competent in this field (3).

⁹ i-PAVED: information about physical activity to reduce vascular erectile dysfunction

3.4. CAPACITY OF FUTURE HEALTH PROFESSIONALS

3.4.1. METHODS - STUDIES IV AND V

Study IV (4): The aim was to translate and psychometrically test the Danish version of the questionnaire Students' Attitudes towards Addressing Sexual Health (SA-SH-D).

Study V (5): The aim was to investigate Danish healthcare professional students' attitudes towards addressing sexual health in their future professions, and to assess differences in perceived competence and preparedness depending on professional programme.

Study IV (4): The methods included, first, a translation and cross-cultural adaptation (including face validity) of the original SA-SH (142) to Danish, and second, a psychometric testing of validity and reliability of Danish Attitudes towards Addressing Sexual Health (SA-SH-D), the translated questionnaire.

Study V (5): Using SA-SH-D, the method was a cross-sectional observational study of Danish health professional students' attitudes towards addressing sexual health in their future professional work. The reporting of the study followed the STROBE guidelines (STrengthening the Reporting of OBservational studies in Epidemiology) (155), which was supplemented with the relevant parts of the CHERRIES checklist (Checklist Reporting Results of Internet E-Surveys) (156).

3.4.1.1. THE SA-SH-D QUESTIONNAIRE

The SA-SH-D consists of 22 items distributed across four domains: feelings of comfortableness (questions 1-9), fear of negative influence on future patient relations (questions 10-15), future working environment (questions 16-18), and educational needs (question 19-22) (142). Items within the questionnaire are answered on a Likert scale with five options: disagree, partly disagree, partly agree, agree, and strongly agree (4,5). SA-SH has a possible total score value between 22-110, and three response patterns: uncomfortable and unprepared (score 22-56), comfortable and prepared in some situations (score 57-79), and comfortable and well prepared to work with sexual health in their future profession (score 80-110) (157).

3.4.1.2. SETTINGS

Study IV (4): The translation and psychometrics of SA-SH-D was conducted at UCL, University College in Denmark.

Study V (5): The survey was conducted at nursing, occupational therapist and physiotherapist programmes at all six Danish University Colleges in Denmark.

3.4.1.3. PARTICIPANTS

Study IV (4): In the face validity assessment: two groups of physiotherapy, nursing, and occupational therapy students participated. In the content validity, floor and ceiling effects, and construct validity assessment, the 40 participants were students at two interprofessional courses (sexology and project leadership) at health professional programmes.

Study V (5): The participants were bachelor students in their final semester enrolled on healthcare professional programmes at all six University Colleges in Denmark.

3.4.1.4. PROCEDURES

Study IV (4): An internationally recognized and recommended procedure, applied as a basis for a formalized translation and adaptation process of the SA-SH to the Danish version, SA-SH-D was performed according to the guidelines by Guillemin (158,159). The procedure for the translation and face validity is provided in Paper IV, and the primary steps are shown in Table 4.

Table 4. The steps of the translation, adaptation and testing of the SA-SH-D

Steps	Procedure
Step 1 Forward translation	SA-SH-D was translated by two independent, bilingual, qualified translators. The translators had the target language (Danish) as their mother tongue and the original language (Swedish) as their working language.
Step 2 Synthesis	The first author together with the two translators performed a synthesis of the translations.
Step 3 Back translation	Three independent bilingual translators having the original language as their mother tongue performed the back-translation.
Step 4 Committee and face validity	Committee review by the research group and the translators composed a preliminary version of SA-SH-D, which was assessed in two focus groups.
Step 5 Content validity index	CVI was assessed by health professional students

Study V (5): At each University College, a project ambassador for each educational programme assisted with the data collection that was performed by using the Danish version of “Students’ Attitudes towards Addressing Sexual Health (SA-SH-D) (4). Further procedures of the data collection, including steps to promote the survey response rate are provided in Paper V and shown in Table 5.

Table 5. Data collection procedure – including steps to promote the response rate

Steps	Procedure
Project ambassador	At each UC, the educational manager appointed a project ambassador for each educational programme. The ambassadors received written information on how to assist with and ensure the quality of the data collection.
SA-SH-D distributed via SurveyXact	The data collection was performed by using SA-SH-D (4), which was distributed online via the web-based application SurveyXact. Prior to the distribution of the SA-SH-D, the ambassadors pilot-tested the usability and technical functionality of the online version.
The day of the data collection	The day of the data collection was optimized for each educational programme with each project ambassador selecting appropriate dates for the data collection.
Reminder to the mbassadors	Reminder emails were sent to the ambassadors the day before the initiation of the data collection.
Provision of SA-SH-D to the students	Each ambassador presented written information about the voluntary survey, the purpose of the study, the expected time expenditure of the survey, anonymity, a short video introduction of the survey, and an open link to the online version of SA-SH-D on the students’ respective learning platforms.
Time to complete SA-SH-D	13 (of 16) ambassadors introduced the study and the SA-SH-D to the students in a face-to-face session where the students were given time to complete the SA-SH-D.
Reminding to the students	During the data collection period, ambassadors were asked twice by email to remind the students about answering the SA-SH-D.
Motivating the ambassadors	To motivate and engage the ambassadors they received feedback on the current response rate on their specific educational programme together with the reminders.
Data collection	The data were collected from 26 August to 24 October 2019.

3.4.1.5. DATA PROCESSING, ANALYSIS AND STATISTICS

Study IV (4): The data analysis for the psychometric tests: CVI, construct validity, floor and ceiling effects and reliability was the following. For the CVI, the relevance of each included item was assessed with a CVI test on a four-point scale (1 = extremely relevant, 2 = quite relevant, 3 = slightly relevant, 4 = not relevant). The scale was dichotomized by collapsing extremely relevant/quite relevant and slightly relevant/not relevant respectively. The items were considered to be relevant if the item level CVI >0.78 per item and if the sum of the CVI for each item > 0.90 (160,161). Construct validity was tested with a multi-item correlation matrix of the factors found in the original Swedish SA-SH factor analysis (142). Item internal consistencies were considered satisfactory if an item correlated 0.40 or more with its factor (162). Floor and ceiling effects of the SA-SH-D were tested. Floor effects were considered to be present if $\geq 15\%$ scored an item as 1 (lowest possible score), and ceiling effects were considered to be present if $\geq 15\%$ scored an item as 5 (highest possible score) on the SA-SH-D (163). Test of reliability was performed with internal consistency reliability with Cronbach's alpha, with a Cronbach's of 0.70–0.95 considered as good (163). Descriptive statistics were presented in percent, median, mean, standard deviation, and response value frequencies. Item-scale correlations were analysed with Pearson's method (4).

Study V (5): For the data processing, the responses 'strongly agree and agree' were collapsed and reported positive for positively loaded items. For negatively loaded items, the responses 'disagree and partly disagree' were collapsed and also reported as showing a positive attitude. The response option 'partly agree' was not reported as a positive or a negative attitude. The single responders total score of the SA-SH-D was calculated with points from 1 to 5, where 5 was the most positive value and 1 the most negative value. For items 1 to 8, 15, and 19 to 22 the responses were coded 1= disagree, 2= partly disagree, 3=partly agree, 4= agree, and 5=strongly agree. Items 9 to 14 and 16 to 18 have reversed coding.

Descriptive statistics: Characteristics of the sample were presented by gender, age and educational programme. Descriptive statistics were presented in numbers and percentage for gender and educational programmes, and for age in mean and standard deviation (SD). Each item of the SA-SH-D was presented with descriptive statistics. The response rates in the categories 'disagree' to 'strongly agree' for each of the 22 items were illustrated by horizontal bar charts in percentage.

Inferential statistics: A one-way ANOVA was conducted to determine if there were any statistically significant differences between the mean of the total score of SA-SH-D between the nursing, occupational therapy and physiotherapy programmes, taking into account the random variation between individuals within each programme (within-programme variation). A post hoc multiple comparisons Tukey's test was applied. Outcome variables were the ordinal variables of the total score for the single

responder. Exposure variables were the nominal categorical variables: educational programme defined as nursing, occupational therapy and physiotherapy. Only responders with a complete dataset were included in the ANOVA analyses. Significance level was set at $p < 0.05$. STATA 16.0 (StataCorp, College Station, Texas, USA) was used for the analyses.

3.4.2. ETHICS – STUDIES IV AND V

Study IV (4): The project received ethical approval from the Danish Data Protection Agency (154).

Study V (5): Ethical considerations followed the directions of the Helsinki Declaration and ethical approval was applied in line with the recommendations of the General Data Protection Regulation (GDPR) and the Danish Data Protection Agency (154).

3.4.3. RESULTS – STUDIES IV AND V

Study IV (4): In the translation and adaptation of the SA-SH-D, the first two steps of the translation process showed only minor semantic disagreements between the two translators. In the third step, consensus was reached among the translators and the researchers and this final version of the questionnaire was tested for face validity in the fourth step. The face validity groups had agreed that all items in the questionnaire were easy to understand, and the questionnaire was easy to complete. There were also minor changes in phrasing added in this fourth step of the translation process. The SA-SH-D procedure classroom handed out had a response rate of 92% for students in the sexology course and of 89% for students in project leadership, which resulted in 40 participating students. In the CVI, all questions had an I-CVI of 0.82–1.0. The scale-level CVI average (S-CVI/Ave) was 0.95. The results of the I-CVI and the S-CVI/Ave show that the SA-SH-D is highly relevant. Item descriptive statistics are presented in Paper IV, Table 2. All items (except two) in the factors showed standard deviation values lower than 1.0 (0.75–0.98), which indicates that the precision is acceptable. There was a tendency towards floor and ceiling effects; however, only items 20 and 22 had a median of 5 (strongly agree). The internal consistency reliability of the first test gave a Cronbach's of 0.674 with variance of 0.614–0.714 if the tested item was deleted. The Cronbach's alpha values for the factors from the SA-SH in the SA-SH-D are presented in Paper 4, Table 4.

Study V (5): Of the 18 invited educational programmes, 16 participated in the survey. The overall response rate was 48%; the individual programme response rates were 44% (322) for nursing students, 70% (143) for occupational therapy students and 43% (119) for physiotherapy students. A Flowchart of survey response is provided in Paper V, Figure 1. Demographic characteristics of the Danish health professional students (n=584) are presented in Paper V, Table 1.

Approximately a quarter of the students felt comfortable about informing future patients about sexual health, initiating a conversation about sexual health, discussing sexual health with future patients regardless of their sex, age, cultural background or sexual orientation, and disagreed that they felt unprepared to talk about sexual health with future patients. A smaller proportion of the students felt comfortable about discussing specific sexual activities with future patients (Paper V, Figure 2).

Around one third of the students disagreed that they would feel embarrassed if future patients were to talk about sexual issues. A smaller proportion of the students disagreed that future patients might feel embarrassed if they, as professionals, were to raise the subject, and likewise a smaller proportion were not afraid that future patients might feel uneasy if they, as professionals, were to talk about sexual issues. Half of the students were not afraid that conversations regarding sexual health might create a distance in the relation between the patients and them as professionals. Approximately a quarter of the students did not believe that they would have too much to do in their future professions to have time to handle sexual issues; around one third of the students believed that they would take time to include sexual issues in their future profession (Paper V, Figure 3).

More than half of the students were not afraid that their future colleagues would feel uneasy if they were to bring up sexual issues with patients, and nearly one third of the students were not afraid that their future colleagues would feel uncomfortable in dealing with questions regarding patients' sexual health. Nearly half of the students did not believe that their future colleagues would be reluctant to talk about sexual issues (Paper V, Figure 4).

A very small proportion of the students had been taught about sexual health in their education. A smaller proportion of the students had sufficient competence to talk about sexual health issues with their future patients. A majority of the students thought that basic knowledge about sexual health should be included in their education and that they needed to be trained to talk about sexual health as part of their education (Figure 11 (and Paper V, Figure 5)).

PHYSICAL ACTIVITY TO REDUCE VASCULAR ERECTILE DYSFUNCTION

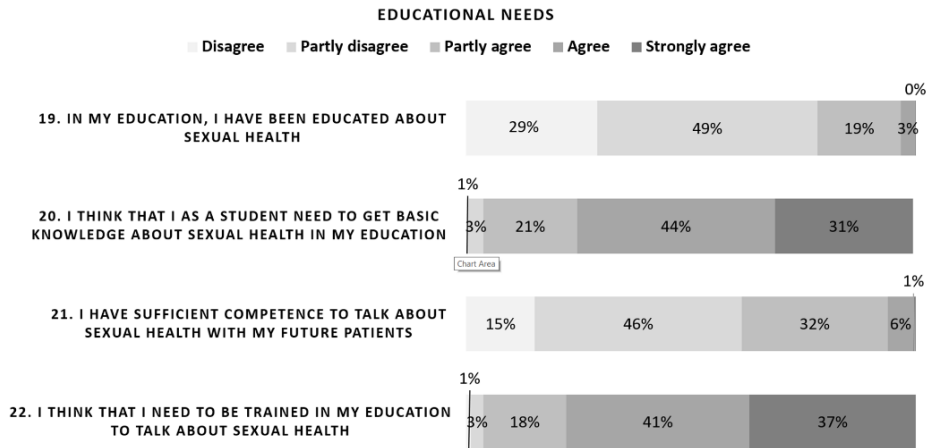


Figure 11. HCP students' educational needs regarding sexual health (n=576).

For the total score, there was a significant difference between groups as determined by one-way ANOVA. A Tukey post hoc test revealed that the total score was significantly higher (2.7 ± 1.1 , $p = .034$) in the physiotherapy programme group (66.3) compared to the occupational therapy programme group (63.7). There were no significant differences between the other programmes. All three programmes had a total mean score between 63.7-66.3 in the SA-SH-D, placing the students in the low-end of the response class: 'comfortable and prepared in some situations (score between 57-79)'.

CHAPTER 4. DISCUSSION

This thesis is based on five studies (**I, II, III, IV, V**) (1-5). The aim of the project was to develop the complex intervention Physical Activity to reduce Vascular ED (PAVED) for men with vascular risk factors for ED in term of 1) the physical activity level needed to reduce vascular ED, 2) the acceptance and perspectives of men with cardiovascular diseases on health professionals address of and communication about sexual health, 3) health professional students' attitudes towards addressing sexual health. The latter entailed a translation and psychometric test of the 'Healthcare Students' Attitudes towards Addressing Sexual Health' questionnaire.

The discussion is structured as follows. First, the key findings of the five studies and a logic model of the project are presented, followed by a discussion of the evidence of the level of PAVED, including dissemination of **Study I**. Then, the potential receivers' acceptance and perspectives (**Studies II and III**) are discussed, followed by discussions of the psychometrics of SA-SD-D (**Study IV**) and the potential providers' attitudes, competence and capacities to address sexual health (**Study V**). This leads up to a discussion on how the five included studies can contribute to the six elements of the Adapted MRC Development phase. Finally, the methodological considerations are discussed and immediately followed by the conclusion of the project.

4.1. KEY FINDINGS

Firstly, with regard to the development of the physical activity component of PAVED, Study I, synthesized the major findings of the physical activity level. **Study I** indicated 40 minutes of supervised, aerobic physical activity of moderate intensity, 4 times weekly for 6 months to reduce ED for men with vascular ED, and further that the physical activity of moderate intensity can be successfully supplemented with intervals of physical activity of high intensity (1).

Regarding the communicative component, i-PAVED, **Study II** indicated, that the men had experienced that health professionals either had not addressed or only briefly addressed sexuality and ED. Men's acceptance was identified and interpreted as the themes: 'expression of interest', 'not bothersome, yet a potentially emotional effort', 'in harmony with men's attitudes and values', 'understandable and meaningful', 'better understanding' and 'self-care and motivation' (2).

Study III indicated that men wanted health professionals to communicate about ED, as it was perceived as a major problem diminishing masculinity, affecting their relationship and tabooed by health professionals. The men wanted help to self-help, which may be possible with the aid of competent health professionals' communication about how to prevent, reduce and cope with ED - including information about physical activity to reduce vascular ED. The men wanted health professionals to give

permission to talk about ED in various contexts: general information in groups, sexual counselling for individuals and couples and written material (3).

Regarding potential future health professionals' competence and capacity to provide the communicative component i-PAVED, **Study IV** tested and evaluated the Danish version of the Students' Attitudes towards Addressing Sexual Health questionnaire (SA-SH-D). The face validity showed that SA-SH-D was easy to understand and complete. The CVI showed high relevance. The construct validity analysis indicated that the precision is acceptable (4).

Study V showed that health professional students across programmes share the same difficulties addressing sexual health. Less than a quarter of the students felt comfortable dealing with sexual health issues with future patients. Many of the students thought future patients might feel embarrassed and uneasy if they as professionals were to talk about sexual issues. A majority of the students reported lack of education and competence in the field of sexual health, and that their education should include knowledge and communication training in the field of sexual health (5).

4.1.1. LOGIC MODEL OF THE PROJECT

A logic model can help clarify causal assumptions by depicting the intervention (13). There is no uniform template for developing logic models. However, the most common approach involves identifying a logical flow that starts with specific planned input and activities and ends with specific outcomes or impacts, often with short-term and intermediate outcomes (13). A logic model of the project: Development of the complex intervention: Physical activity to reduce Vascular Erectile Dysfunction (PAVED) is presented in table 6.

Table 6. Logic model of the project

System Characteristics	Resources Available	Activities	Mechanisms of Change	Short and long-term Outcomes
Study I: Lack of evidence of the level of PAVED.	Study I: Identified theory, mechanisms and evidence of PAVED.	Study I: Systematic review of the level of PAVED.	Study I: Evidence of the level of PAVED. Widely disseminated.	Study I: Recommendation and guidance on the level of PAVED. Design of PAVED

Studies II and III: Unclear knowledge about the acceptance and perspectives among men in cardiac rehabilitation on HPs' ¹⁰ address and communication about i-PAVED ¹¹ .	Studies II and III: Collaborative municipal leaders, HPs and men participating in cardiac rehabilitation.	Studies II and III: Understanding of acceptance, perspectives and needs among men in cardiac rehabilitation on HPs' address and communication about i-PAVED.	Studies II and III: Clarification of men's' acceptance, needs and prerequisites regarding HPs' provision of i-PAVED. Municipal dissemination.	Studies II and III: Assurance to HPs about men's acceptance and perspectives on addressing and communicating about ED, sexuality and i-PAVED. Design of PAVED.
Studies IV and V: Lack of questionnaire to measure HP students' attitudes and capacity towards addressing sexual health in their future profession, about which knowledge was unclear.	Studies IV and V: Network at UC in DK. Support from UCL.	Studies IV and V: Cross-cultural adaption and testing of SA-SH-D, and use of SA-SH-D in a survey of Danish HPs students' attitudes and capacity to address sexual health in their future profession.	Studies IV and V: SA-SH-D is provided. Indications of Danish future HPs' insufficient competence and capacity as well as a need for education in the field of sexual health. Planned dissemination (cancelled due to the pandemic).	Study V: Recommendation of sexual health being a compulsive theme in Danish HPs' educational programmes and curricula.
<p style="text-align: center;">Development of the complex health intervention Physical Activity to reduce Vascular Erectile Dysfunction</p>				

¹⁰ HP: Health Professionals

¹¹ I-PAVED: Information about Physical Activity to reduce Vascular Erectile Dysfunction

4.2. EVIDENCE OF THE REQUIRED LEVEL OF PAVED

In **Study I**, physical activity was found to be effective in reducing vascular ED (1). A recent study by Allan confirmed the results of **Study I**, presenting evidence of physical activity being ‘*an extremely effective treatment*’ for ED for men with vascular risk factors (11). A 2019 umbrella review strengthened the evidence for the mechanism of PAVED describing that regular physical activity causes repetitive increases in blood flow, vascular shear stress and increase in the release of nitric oxide, and showing that physical activity interventions had the largest average effect size across all ED behavioural treatments (40). An overview of reviews found that physical activity currently is one of the only non-pharmacological interventions for which efficacy has been confirmed in large, well-designed clinical trials (164). A Danish RCT study investigating sexual rehabilitation for men with cardiac diseases, intervening with three weekly sessions of 60 minutes of supervised aerobic physical activity for 12 weeks, resulted in a reduction of ED from a mean IIEF score of 11.2 at baseline to a score of 14.5 at follow-up (165), which supports the results of **Study I**.

In **Study I**, the training modality for all the intervention groups was aerobic (1). According to a review, there is a significant, positive relationship between aerobic exercise intensity and endothelial function (93). The aerobic modality was in nearly half of the studies (165-169) supplemented by resistance training (1). The finding that aerobic exercise improves endothelial function whereas resistance training has beneficial maximising effects on the level of testosterone, which regulates nearly every component of erectile function (11) supports the advantage of supplementary resistance training. **Study I** indicates moderate intensity and intervals of high intensity to be a key elements in the efficiency of the physical activity (1), which in line with findings in systematic reviews, umbrella reviews and meta-analyses (7,11,40,56). According to Allen, moderate-intensity physical activity shows a similar risk association to high-intensity physical activity for ED (89), and regular aerobic exercise bouts at a moderate (rather than high) intensity would be more beneficial (11). In contrast, low-intensive physical activity, such as walking, will probably be ineffective, because the body is not sufficiently stressed and the beneficial vascular adaptations will be minimal (11). In **Study I**, nearly one third of the studies included walking (170), brisk-walking (171) and walking-hiking¹² (172), and the intervention groups, achieved reduced ED. A meta-analysis shows that walking interventions increased VO2 max in previously sedentary adults (173). Thus, the modality of physical activity that compares to moderate intensity seems to depend on the actual fitness and modality should be continuously adjusted along with improved fitness. In **Study I**, most of the intervention groups performed a progression of the level of physical activity during

¹² Addition to the data in the review

the training period (168,170,171) and/or the physical activity intensity was defined corresponding to a specific percent interval of maximum heart rate or perceived exertion (167-170,172,174).

Health professionals' provision of individual supervision, guidance and counselling to improve the physical activity seem to be an active component in the design of PAVED, as it was provided for most of the intervention groups in **Study I** (165-171,174-176). Health professionals provided men with detailed information on the importance of physical activity in improving penile vascularization and thereby reducing ED, and it was carefully explained that good results, regarding reduced ED, depended on maintaining regular physical activity (172). Men in the intervention groups were more physically active than in the control group, indicating that the expected effects of physical activity on reducing ED are likely to motivate men to be more physical active (171) and emphasizing the importance of health professionals' provision of the active component, i-PAVED. Likewise, reviews have found that supervision heavily influences the success of exercise interventions (11).

The expected training duration to achieve a minimal clinically important difference of ED is relevant for the development of PAVED. A Minimal Clinically Important Difference score on the IIEF has been established and found to be 4, with variation ranging according to baseline severity (mild: 2; moderate: 5; severe: 7) (177). Nearly all the intervention groups in **Study I** achieved a mean difference in the ED domain indicating a clinically relevant effect. This effect was achieved by a duration of training varying from 1 month to 2 years (1). It is likely that extending physical activity for a longer period would result in a further reduction of ED (172). Nevertheless, regular physical activity should be endorsed as a permanent lifestyle alternation to maintain cardiovascular health over the lifespan (11), and if returning to physical inactivity the gained reduction of ED cannot to be expected maintained.

The number of studies included in **Study I** was limited, their interventions varied, and the effect of various physical activity levels were not directly comparable because of variation in population groups (1). However, Duca et al. estimated that the results of **Study I** were sufficiently evident to be used in developing recommendations for practice (178). According to the overall physical activity level, **Study I** indicates 40 minutes of physical activity of moderate intensity, 4 times weekly for 6 months to reduce vascular ED, which is an overall dose of 160 minutes a week (1). According to the WHO, healthy adults should perform at least 150–300 minutes of moderate-intensity aerobic physical activity or at least 75-150 minutes of high-intensity aerobic physical activity a week (179).

Study I indicates that 40 minutes of supervised, aerobic physical activity of moderate intensity (supplemented with intervals of high intensity), 4 times weekly for 6 months reduces ED for men with vascular ED caused by physical inactivity, obesity, hypertension, metabolic syndrome, and/or manifest cardiovascular diseases.

4.2.1 DISSEMINATION OF STUDY I

The focus of this PhD project was limited to the development phase (Figure 2). However, the process of developing a complex intervention may not follow a linear sequence (12,14). Dissemination is a key element in the implementation phase of developing a complex intervention (Figure 2) (12,14). **Study I** (1) has for example been disseminated in the following research: Exercise guidelines for cancer survivors (180); Relationship between sexual functioning and overweight (181); Cardiovascular exercise protectiveness against sexual dysfunction among men and women (182); Risk and Protective Factors for ED (183); Effects of Exercise Training on Sexual Health in a Cancer Population (184); Guidelines on Sexual and Reproductive Health of the European Association of Urology (185); Development of a Self-Reported screening tool of Erectile Dysfunction (186), and Clinical Implications and Management of Male Obesity-related Secondary Hypogonadism–Pathophysiology (187). According to the MRC, the results should be disseminated as widely and convincingly as possible (14). The results of **Study I** have been disseminated widely in articles and books for researchers and health professionals (188-202). For healthcare prevention and sexual health promotion in the general population the results of **Study I** have been disseminated in Danish and international articles, webpages, newspapers, reports and magazines (203-221).

4.3. PERSPECTIVES OF POTENTIAL RECEIVERS OF PAVED

Studies II and **III** explored acceptance, perspectives and needs among potential receivers of PAVED - men in cardiac secondary prevention and rehabilitation - regarding health professionals' provision of i-PAVED (Figure 7).

4.3.1. ACCEPTABILITY

Study II was perceived at being the first to explore how acceptance of cardiac health professionals' address of sexuality, ED and i-PAVED can be identified in men's narratives (2). The seven components of TFA were deemed useful in the deductive analysis, where men's anticipated or experiential acceptance was identified as 'Expression of interest', 'Not bothersome, yet a potentially emotional effort', 'In harmony with men's attitudes and values', 'Understandable and meaningful', 'Better understanding', and 'Self-care and motivation'(2). The results of **Study II** are summarized in Figure 10.

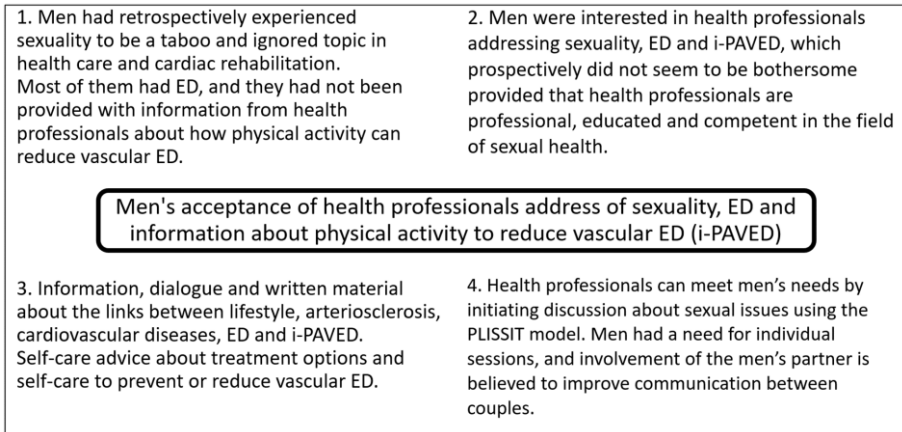


Figure 10. Men's acceptance of health professionals' address of i-PAVED

The men's apparently positive narratives could be perceived as an unreserved accept of the intervention; however, a prerequisite for the men's prospective acceptance of health professionals' address of sexuality, ED and i-PAVED was the ethical aspect that the professionals should be educated and competent in the field of sexuality (2). This novel result was essential as reviews show that health professionals – including the cardiac – often lack education, competence and communication training in the field of sexuality (100,101,107,117,136,222).

According to ethical aspects of men's integrity, the PLISSIT model or the EX-PLISSIT model was interpreted as a way to address sexuality (223,224). Men's experience that cardiac health professionals never, rarely or only briefly address sexuality and ED was substantiated by other Danish and European studies (94,95,103,117,222). Studies have found that healthcare professionals are influenced by the norms and taboos of their culture, and that the view on sexuality as a taboo subject that lies outside their consequence prevents them from engaging in this area of practice (106,225-227). This reluctance forms a barrier between patient and health professional, which prevents satisfactory healthcare to patients (113).

Interpreted as men's acceptance were the findings: men's feelings of interest, motivation, open-mindedness, their feelings of speechless and frustration if relevant topics regarding sexuality were not addressed, and their experience that the address of sexuality was not a burden, bothersome, annoying or offensive (2). Previous studies have found that patients with cardiovascular diseases have positive attitudes towards health professionals addressing sexual issues (46,228,229) and that patients, regardless of age, feel embarrassed if the health professionals lack understanding of their sexual health (230,231). Men interpreted as shy did not perceive health professionals' address of sexuality as annoying, bothersome or offensive either (2), which was an important new finding because fear of offending patients is found to keep health professionals from addressing sexual issues (106,107,112,117,136). Nevertheless, shy

men would probably never initiate a conversation about sexuality themselves. Therefore, the health professionals were recommended to initiate address of the topic, and according to patients, need to develop a comprehensive management plan regarding sexual problems (2) – as established in international studies over the last decade (10,46,106,117,228,230-234). Consequently, health professionals should be prepared to address sexuality.

The men lacked knowledge about PAVED and a new finding in **Study II** was that men found the mechanisms of vascular ED easy to understand, meaningful, relevant and acceptable to be addressed. Therefore, in **Study II**, health professionals were recommended to address ‘how’ and ‘why’ PAVED works (2) - in line with previous studies (126,132). Lack of knowledge especially regarding physical activity and other modifiable lifestyles factors’ effect on ED, is not a new finding (126,132,235). Health professionals’ address of the link between cardiovascular diseases, sexuality and ED may promote a better understanding of vascular ED for the men themselves as well as their possible partners (2). Most of the men with ED did not remember being given any possible cause of their ED or diagnosis (2), and ED being under-diagnosed in cardiac rehabilitation has found before (97,98). The men’s experiences of inexplicable ED could also lead to miscommunication between partners, which was also found in a systematic review (236). Providing men with the needed understanding of potential causes of their ED, together with other diagnostic examinations, health professionals’ dialogue with men regarding cardiovascular risk factors for ED was interpreted as a facilitator for better understanding ED (2).

The men wanted and prospectively accepted the health professionals’ information, dialogue, self-care advice, treatment options and written information about how to prevent and reduce vascular ED (2). Such provision of i-PAVED may improve the men’s belief in their own capabilities with regard to acting on their ED and sexual life, and be beneficial for the men’s self-efficacy regarding their sexual performance and relationship (2). Previous reviews and patients’ perspective studies in the cardiac ward recommend information about ED and treatment, sex counselling and written information (10,11,94,228,229). Despite the interview focus on a rather specific theme regarding health professionals’ provision of i-PAVED, the men requested broad and detailed information and individual sessions, and the health professionals’ address should cover various aspects of sexuality and be tailored to the men’s life situation (2), which could be interpreted in terms of men wanting ‘the whole package’ – in line with previous reviews (10,236,237).

Generally, the men expected that the address of i-PAVED might increase their own and other men’s motivation and self-efficacy in terms of being more physically active (2). Previous reviews have indicated information about the effect of physical activity on ED to be a potential motivator for men to increase their level of physical activity and thereby improve their lifestyle and overall cardiovascular health (1,52,66,238); however, this has not previous been found in studies from the perspective of men with cardiovascular diseases.

The results of **Study II** indicate a need to prepare pilot testing of PAVED in cardiac secondary prevention and rehabilitation, as the active communicative component i-PAVED seems to be prospectively acceptable to men – the potential receivers of PAVED. The results of **Study II** identified a need to ensure that health professionals have competence in the field. To meet the needs of the men, sexual health was recommended to be included as a compulsory theme in the basic health professional educational programmes and as a part of continuous health professional development (2). The results can be useful in designing the i-PAVED component by presenting the men's perspectives (Figure 12).

4.3.2. NEEDS, PREFERENCES, BELIEFS AND PERCEPTIONS

Study III was the first study focusing on men's perspectives on health professionals' communication about i-PAVED, and it generated insight into men's perspectives, needs, preferences, beliefs and perceptions regarding cardiac health professionals' communication about i-PAVED (3) (see Figure 12).

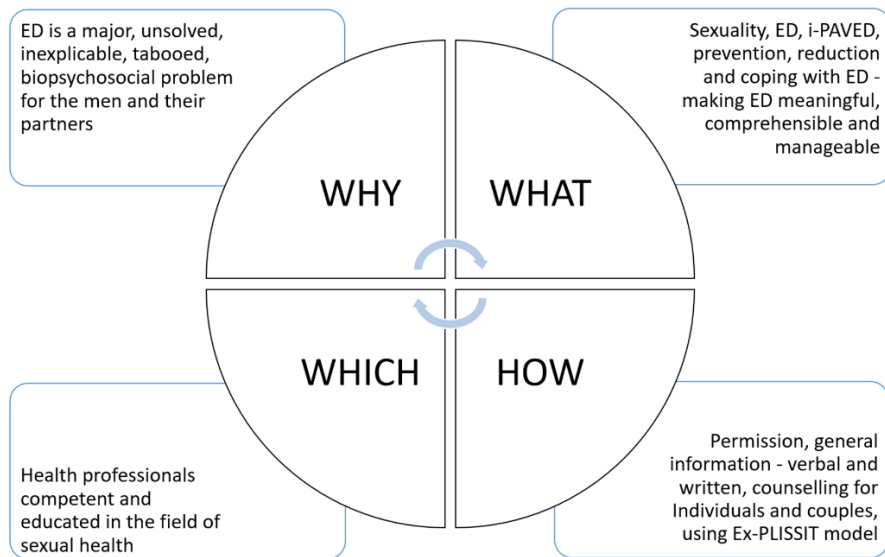


Figure 12. Men's perspectives on HPs¹³ communication about i-PAVED¹⁴.

Firstly, 'why'. In **Study III**, it was interpreted that the men had an unmet need for health professionals' communication about ED and i-PAVED. A recent scoping review found that health professionals rarely provide sexual health interventions to

¹³ HPs: Health Professionals

¹⁴ i-PAVED: information about Physical Activity to reduce Vascular ED

patients in cardiac rehabilitation (10). **Study III** found that ED was a major problem affecting the men's masculine identity and causing emotional distress. Due to lack of 1) knowledge on cardiovascular risk factors, 2) examination, 3) diagnosis and 4) medical solution, ED became an uncertainty and a mystery to men and their partners that negatively affected their intimacy and relationship. The men searched for meaning and solutions to their ED (2). In **Study III**, health professionals' multidisciplinary, integrative and biopsychosocial (39,239) approach in communication was considered appropriate to meet the needs related to the men and their partners' psychosocial concerns about ED (3).

Secondly, 'what'. In **Study III**, it was interpreted that men needed health professionals' help to self-help. The preferred content of health professionals' communication was general information: 1) simple theoretical, anatomical and physiological explanations on ED, 2) how and why PAVED and other lifestyle factors can work, prevent and reduce ED, 3) what can be done about ED, 4) what men can do themselves, 5) what aids are available and 5) how to cope with ED and improve intimacy (3). Health professionals' application of a salutogenetic framework of comprehensibility, manageability and meaningfulness (39,240) was considered to promote men's understanding and the meaningfulness and manageability of the stressor ED, as well as men's motivation to be physically active (3).

Thirdly, 'how'. In **Study III**, it was interpreted that the men had experienced ED as a taboo topic for health professionals. A recent study found that cardiac nurses in Germany rarely practice sexual counselling, sexuality being a silent phenomenon (222). They are inhibited talking about such a taboo topic and feel that they are not responsible for discussing sexual concerns or unprepared to do so (222). The men in **Study II** needed health professionals' initiative and explicit communicative Permission to discuss ED and i-PAVED. Consideration regarding how health professionals should communicate pointed to the ex-PLISSIT model (223,224). Limited Information could be useful in the form of verbal communication, patient-education, illustrative teaching, dialogue regarding general information and written material. Specific Suggestions should be addressed in individual sessions and sessions for couples, which were preferred as appropriate contexts for specific information related to sexuality and ED (3).

Fourthly, 'which'. In **Study III**, it was interpreted that insufficient consultations can lead to men's feelings of rejection, shame and embarrassment and thereby threaten or destroy the patient-professional relationship. The men believed that i-PAVED in principle could be provided by any type of health professional. However, a prerequisite was that health professionals' address of sexuality, ED and i-PAVED had to be based on professionalism and education in the field of sexual health. To ensure this, the health professionals' educational programmes should include basic knowledge about sexual health promotion. A recent study found that cardiac nurses are in need of specialized knowledge and communication skills to feel comfortable to discuss sexual concerns with heart failure patients (222).

In **Study III**, the results of the analysis of the perspectives of potential receivers of PAVED regarding the active component i-PAVED showed, just like **Study II** (2), that the men wanted ‘the whole package’ regarding health professionals’ communication about i-PAVED. The above questions of why, what, how and which, regarding health professionals’ communication about i-PAVED (see Figure 12), condense essential aspects in the development phase of an intervention (13).

4.3.2.1. DISSIMINATION OF STUDIES II AND III

The results of **Study I** and the preliminary results of **Studies II and III** were disseminated at staff meetings at the municipal cardiac secondary prevention and rehabilitation facility in December 2019 and January 2020. The participating head of the organisation and the staff found the intervention PAVED relevant and expressed interest to be involved in further development and design of PAVED.

4.4. PERSPECTIVES OF POTENTIAL FUTURE PROVIDERS

Studies IV and V were conducted involving health professional students. In **Study IV**, SA-SH-D was provided (4), and it was used in **Study V** to investigate the potential future providers of PAVED - Danish health professional students’ - attitudes and perceived competence towards addressing sexual health (5).

4.4.1 THE SA-SH-D

In the translation of SA-SH-D consensus was reached among the translators and the researchers, with approval of the back-translated version by the researchers who created the original SA-SH (142). In **Study IV**, this final version of the questionnaire was tested for face validity in the fourth step, which resulted in minor changes. The procedure of handling out the SA-SH-D in classrooms resulted in a high response rate (4), which was expected as face-to-face administered questionnaires often increase response rate (241), and thus the response rate was higher than the response rate for the original SA-SH (occupational therapy 32%, nursing 23%, physiotherapy 23%) (142). In step five, the 40 participating students tested the validity. All questions had an I-CVI of 0.82–1.0 (4). An I-CVI of 0.78 or higher can be considered evidence of good content validity (161). Regarding the construct validity, the correlation scores were satisfactory to suggest that all items included in the factors should be kept in the SA-SH-D (4). The internal consistency reliability test gave a Cronbach’s α of 0.67, which is acceptable, as a criterion of 0.70 - 0.90 is proposed as measuring good internal consistency (163). In comparison, the original SA-SH had a Cronbach’s α of 0.61 (142). In **Study IV**, the SA-SH-D showed good face, content, and construct validity, as well as internal consistency reliability (4).

4.4.1.1. USE, TESTING AND ADOPTION OF SA-SH-D

SA-SH-D meets a need for a questionnaire in the field. SA-SH-D has been used in a controlled educational intervention study (138) and to investigate health professional students' attitudes towards working with sexual health (242). According to Ware, to ensure the efficiency of SA-SH-D, a translation should be re-examined and rephrasing of the items should be considered (162). The psychometric properties of SA-SH-D, involving 111 students, was assessed (243). Seven of these participated in a Think-aloud study, which identified only few challenges with the wording, and the SA-SH-D was found relevant, comprehensive and comprehensible (243). Cronbach's α for the total scale was 0.84 indicating a good internal consistency (243). The 2-week interval test-retest showed, when allowing for one-point difference, a percentage agreement ranging from 88.2% - 100% per item and 95.2% for the total scale, and SA-SH-D was considered able to produce acceptable stable scores over time and consistent measurements (243). SA-SH-D was adapted in the questionnaire 'Professionals' Attitudes towards Addressing Sexual Health' (PA-SH-D), which was used to investigate municipal healthcare professionals' attitudes towards working with sexual health (244) and the influence of a skills development course on health professionals' attitudes and practice in municipal rehabilitation of sexual problems (245).

4.4.2. DANISH HEALTH PROFESSIONAL STUDENTS' CAPACITY

Study V was the first to examine Danish nursing, occupational therapist and physiotherapist students' attitudes towards addressing sexual health in their future profession. A total mean score between 63.7 and 66.3 placed the entire health professional programme groups in the low-end of the response class: 'comfortable and prepared in some situations (score 57-79)' (157). In comparison, a Swedish survey found a more positive attitude among nurses and occupational therapy students compared to physiotherapy students (135). Danish health professional students lack competence, preparedness and education in the field of sexual health, which is comparable with previous international research in the field (101,115,135,139,141,246,247). The future Danish health professionals are probably not sufficiently prepared to address the preventive effect of physical activity on ED.

Study V showed that most of the Danish health professional students did not feel comfortable with discussing sexual health issues with future patients regardless of their age (5). This result is comparable to the findings of health professional students' and health professionals' ageism, lack of knowledge and confidence regarding older adults' sexuality, and perceptions that their sexuality lies outside health professionals' scope of practice (101,106,107,116,135,136,234). This is a barrier to older adults seeking the sexual health advice (101) they need, considering that many have maintained sexual desire combined with the highest prevalence of sexual dysfunction (230,248,249). **Study V** showed that most of the Danish HCP students did not feel comfortable with discussing sexual health issues with future patients, regardless of

their sexual orientation (5). Systematic reviews have also found that health professionals lack knowledge and education in providing sexual health services for non-heterosexuals (101,106,136,250), although they report higher degrees of sexual distress than heterosexuals (251). **Study V** showed that most of the health professional students acknowledge that future patients might feel embarrassed if the students, as professionals, were to bring up sexual issues (5), which is a result that confirms the previously found sexual ‘two-way taboo’ in healthcare (100,103,106,136). A recent nationwide Danish study shows that Danish patients rarely experience health professionals as initiators of conversations regarding sexual health (252). **Study V** revealed that few of the health professional students felt that they have been educated about sexual health and have sufficient competence to talk about sexual health with their future patients (5). International reviews have showed that health professionals lack education and have a need for competence in the field of sexual health (10,101,106,107,136,234). Studies have shown improvement in healthcare professionals’ ability to deal with patients’ sexuality issues after participating in sexuality education programmes, regardless of course load and modality (114,115,138,253-258). Healthcare professionals therefore have a need for education in the area of sexual health, regardless of their discipline. In order to improve the performance and comfort level of healthcare professionals in dealing with patients’ sexuality, investments in training is necessary (10,253,254,257,258); however, Danish nursing, occupational therapy and physiotherapy education curricula do not formally address sexual health (259-261).

4.4.2.1 DISSEMINATION OF STUDY V

Dissemination of the results of **Study I** and the preliminary results of **Study V**, the survey of Danish health professional students’ attitudes towards addressing sexual health, planned to take place in sessions at the six Danish University Colleges in spring 2020. However, the six sessions were cancelled due to the COVID-19 pandemic.

4.5. DEVELOPMENT OF PAVED – CONTRIBUTIONS OF THE STUDIES

How the five included studies can contribute to the development and design of PAVED is discussed in relation to the elements of the ‘Adapted MRC Development phase’ (13) (Figure 3).

4.5.1. PROBLEM IDENTIFICATION AND DEFINITION

A starting point is *Problem identification and definition* (13) (see Figure 13).

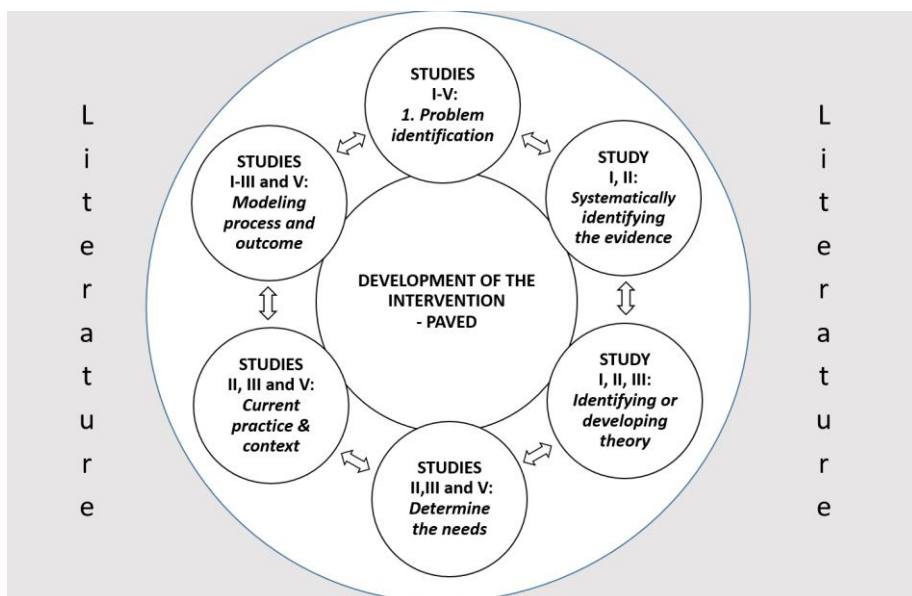


Figure 13. Contributions of the included studies to the development of PAVED

Problems identified in this project were lack of recommendations for physical activity-induced reduction of ED (PAVED), which **Study I** provided (1), as well as a need for developing the component of health professionals' communication about i-PAVED, which was examined in **Study II** (2), **Study III** (3) and **Study V** (5). The identified problem of whether health professionals' address of ED and i-PAVED can be perceived as acceptable for men was explored among men in cardiac secondary prevention and rehabilitation in **Study II** (2), and the identified need for understanding the perceptions of recipients was explored in **Study III** (3). Whether potential future health professionals have the capacity to provide i-PAVED was an identified problem investigated in **Study V** (5). The identified lack of a questionnaire to measure health professional students' attitudes towards working with and communicating about sexual health led to the psychometric study in **Study IV** (4).

4.5.2. SYSTEMATICALLY IDENTIFYING THE EVIDENCE

Identification of the available evidence, ideally through systematic reviews or meta-analyses, needed to be conducted (13). The evidence of the level of physical activity needed to reduce vascular ED was systematically identified in **Study I**, indicating that 40 minutes of supervised, aerobic physical activity of moderate intensity (supplemented with intervals of high intensity), 4 times weekly for 6 months, reduces vascular ED (1), which can contribute to the design of the intervention PAVED. Acceptability of the intervention also needed to be studied (13). The acceptance among potential future receivers of PAVED on health professionals' address of ED and i-

PAVED was systematically explored in **Study II** by use of the TFA (123), indicating that men in cardiac secondary prevention and rehabilitation seemed to prospectively accept health professionals' address of i-PAVED (2). A prerequisite for the men's acceptance was health professionals' professionalism in the field of sexual health (2). However, the men had not experienced health professionals' address of i-PAVED; therefore, acceptability is recommended to be further and retrospectively explored following a future pilot test of PAVED (2).

4.5.3. IDENTIFYING OR DEVELOPING THEORY

By understanding the causal mechanisms, the key components of the intervention can be defined based on the knowledge gained from systematic reviews (13). In **Study I**, theory, physiological mechanisms and causal chains of PAVED were identified in previous reviews (1). New theoretical ideas can be gained by conducting qualitative studies explaining how the intervention components may lead to the desired outcome (13). **Study III**, gained new insight into why, what, how and which regarding health professionals' provision of the communicative, active component i-PAVED (3), which can contribute to the design of i-PAVED (see Figure 12). The analyses in **Studies II and III** (2,3) identified men's prerequisite that health professionals' address of and communication about sexuality, ED and i-PAVED should be based on education, competence and professionalism in the field of sexual health.

4.5.4. DETERMINING THE NEEDS

A thorough understanding of the needs, perceptions and preferences of the recipients needs to be incorporated in the development process (13). The needs, perceptions and preferences of potential future receivers of PAVED were explored in **Study III**, indicating that men in cardiac secondary prevention and rehabilitation requested professional health professionals' communication about ED and how to prevent, reduce and cope with ED – including i-PAVED to be provided in various contexts and in written material (Figure 12) (3). In addition, **Study II**, indicated men's need for health professionals' initiative to address relevant topics regarding sexuality, ED and i-PAVED and a need for individual sessions and sessions involving their partner provided by health professionals educated in the field of sexual health. This finding can be used in designing the component, i-PAVED (Figure 12) (2). It is important to make sure that all types of effective ED treatment are consistently accessible to patients (262). Studies have found that cardiac health professionals must be well-educated and have the skills to inform patients and their partners on sexual issues (263), and that nurses should be provided with knowledge and practical training increasing their comfort in discussion patients' sexual health (264), and a review found that lack of knowledge, competence and education was a barriers for cardiac health professionals' address of sexuality (265). The ultimate goal is to develop an intervention that addresses the clinical problem and fulfils the needs of its users. Therefore, investigating the (care) needs and perceptions of the recipients and providers regarding

the identified problem, on the one hand, and the preferences and capacities with regard to the proposed solution, on the other hand, is crucial (13). In **Study V**, the investigation of future potential providers of PAVED regarding their attitudes, competence and capacity to address sexual health indicated that Danish health professional students have a need for competence, training and education in the field of sexual health (5). Investigation of the needs and perceptions of the current providers of cardiac secondary preventive and rehabilitative interventions was not included in this project.

4.5.5. CURRENT PRACTICE AND CONTEXT

To optimize the delivery of an intervention within its context, identifying the existing intervention practice is valuable during the development process (13). In **Studies II and III**, the existing intervention and current practice were identified from the perspective of the potential receivers – men in municipal cardiac secondary prevention and rehabilitation. Considerations regarding how, what and by whom the intervention is to be used and provided is crucial (13). In **Studies II and III**, the men in cardiac secondary prevention had experienced that a health professional had briefly addressed ED and sexuality in a group session (2); thus, the health professionals' awareness of the men's need for addressing ED and sexuality can be a facilitator for developing PAVED. However, typically, the men had experienced that ED was a taboo topic for health professionals (3), and information about the links between cardiovascular diseases and vascular ED as well as i-PAVED was not currently provided (2). In current practice, there seems to be a gap (Figure 14) constituted by the distance between the men's need for health professionals' communication about ED, sexual health and i-PAVED (3) and the health professionals' capacity to address sexual health and i-PAVED (3).

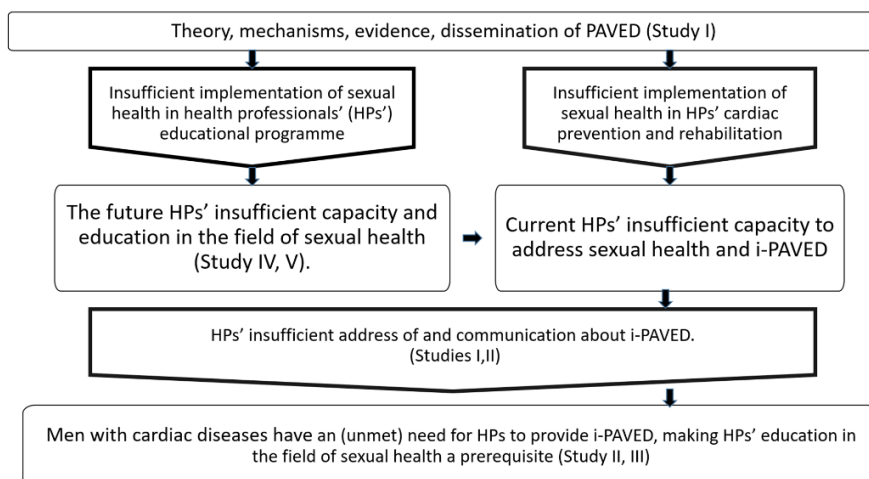


Figure 14. Identified gaps regarding development of PAVED

Careful identification of the implementation route and estimates of the impact on receivers and providers are needed (13). The physical activity component is currently a core intervention in cardiovascular secondary prevention and rehabilitation (8,9,18). Patients with cardiovascular diseases are recommended, aerobic exercise 20-60 minutes, 3-5 times a week, at moderate to high intensity (92), which approximately corresponds to the level of physical activity, which, according to **Study I**, has an impact on vascular ED (1). The estimated impact of the communicative component i-PAVED is prospectively explored from the perspectives of the receivers in **Studies II and III** (2,3). The estimated impact of i-PAVED from the current providers' perspective has not been specifically investigated in this project. However, because the men wanted 'the whole package' in relation to health professionals' address of and communication about i-PAVED, the estimated influence of the current providers is probably substantial if they are not educated to address sexual health; this also applies to the future providers of PAVED, who were investigated in **Study V** (5). In current practice there also seems to be a gap constituted by the distance between the strong evidence of PAVED (**Study I**) (1) and the current cardiac health professionals' address of sexual health and i-PAVED (**Studies II and III**) (2,3) (Figure 14). Guidelines can provide important knowledge to understand the context in which the intervention will be effectuated (13). According to national and municipal guidelines, sexuality is a relevant theme to address during rehabilitation of patients with cardiovascular diseases and their partners, and the theme of sexuality can be discussed in relation to coping with cardiovascular diseases, by health professionals specialized in the field (8,119). The intervention PAVED targets men with vascular risk factors; however, in Denmark both men and women participate in cardiovascular secondary prevention and rehabilitation and therefore the address of sexuality and sexual health should be target both sexes (182).

4.5.6. MODELLING PROCESS AND OUTCOMES

Modelling the active components of the intervention can be started by synthesizing the knowledge gathered from the previous elements of the development phase. Identifying the current problem in a specific context provides insights into current gaps (13). A gap is constituted by the distance between the men's need for health professionals' address of and communication about ED, sexuality and i-PAVED (**Studies II and III**) (2,3) and the future health professionals' insufficient capacity to address sexual health (5) (Figure 14). Recent reviews have found that there remains a significant gap between providers' perceptions and patients' needs regarding sexual health (10,234). Another gap is constituted by the distance between the patients' request for health professionals' professionalism and education in the field of sexual health (**Studies II and III**) (2,3) and the Danish future health professional students' insufficient education in the field of sexual health (**Study V**) (5) (Figure 14). Barriers regarding the proposed intervention among providers of the intervention should be identified (13). In **Study V**, there seems to be a barrier and a gap that is constituted by the distance between the health professional students' reported need for competence and education

in the field of sexual health, and their insufficient competence and education in the field (5) (Figure 14). A recent scoping review found that a lack of health professional education was a reason for not providing interventions related to sexual health in cardiac rehabilitation (10). Therefore, it is recommended that sexual health should be included in health professional educational programmes. The current health professionals' insufficient address of sexual health may be due to the fact that they also have had an insufficient education in the field of sexual health. A recent review also recommended that health professional education and training should incorporate sexual health into its curricula to enhance healthcare professionals' abilities to address sexual health issues (234). Important information can be obtained regarding the required competence of providers and how they should be trained or prepared in delivering the intervention (13). In agreement with Allen, health professionals simply mentioning to men that physical activity might reduce ED, as recommended by the American Urological Association (AUA) (128), will be insufficient to meet the men's needs (**Studies II and III**) (2,3,11). Health professionals need to make it clear that physical activity is their treatment rather than just good advice (11). A discussion of the mechanisms through which physical activity reduces vascular ED and how it reduces risk factors for vascular ED could be helpful (**Studies II and III**) (2,3,11). Health professionals should explain the vascular and physiological factors that contribute to ED and how a physically active (or inactive) lifestyle leads to modification of these systems (**Studies I, II, III**) (1-3,11). Health professionals should also explain that, the effects of phosphodiesterase type 5 inhibitors (PDE5i) are immediate and that they do not appear to have any long-term impact on the underlying vascular dysfunction (**Study I**) (1), and that although metabolic changes caused by regular physical activity take time to occur (6 month), they are likely to correct the underlying pathology of the condition by strengthening the weakened vascular system in men with vascular ED (**Study I**) (1,11).

The findings regarding the evidence of PAVED (**Study I**), the in-depth analysed aspects of men's prospective acceptance (**Study II**), and men's perspectives on why, what, how and which regarding health professionals' communication about i-PAVED (**Study III**) can be included in the design of PAVED as well as in future health professionals' competence development in the field of sexual health in order to improve health professionals' capacity to provide i-PAVED.

4.6. METHODOLOGICAL CONSIDERATIONS

The strengths of **Study I** (1) are the systematic literature search, aimed at including all published RCTs and CTs regarding physical activity to reduce ED and the strict adherence to the PRISMA guidelines. All included trials used comparable measurements to evaluate changes in patient-reported ED. Further, the intervention in all studies was aerobic PA of moderate intensity. A limitation is that the effect of various physical activity levels is not directly comparable across the included studies

because of variation in population groups, inclusion and exclusion criteria, and type of intervention as well as the limited number of eligible studies.

In **Study II** (2), the deductive, concept-driven strategy using the constructs of the TFA strengthened the detailed insight into the various aspects of men's acceptance of i-PAVED. In **Study III** (3), the inductive data-driven approach strengthened the insight into varied aspects of men's perspectives, needs and preferences regarding cardiac health professionals' communication about i-PAVED. A recent study also found the TFA useful in a deductive analysis based on the seven constructs of the TFA (266). Consistency between the data presented and the findings strengthened the validity of **Studies II and III**. The men's lack of experience and knowledge regarding HPs' address of sexuality, ED and i-PAVED influenced **Studies II and III** in terms of the prospective perspectives being dominant in the men's acceptance and perspectives. Thus, further post-intervention research should explore men's concurrent and retrospective acceptance and perspectives of health professionals' address and communication of i-PAVED. In this development project, a pre-intervention study on PAVED, potential receivers of PAVED were involved by exploring their acceptance and needs (**Studies II and III**). A recent review shows that pre-intervention analyses of the needs of potential users are rarely performed (267) and most interventions are solution-driven rather than needs-driven (267)]. Pre-intervention studies involving patients exploring the relevance of an intervention can prevent research waste (267), which is a major problem due to a lack of patient centeredness in research (267). Research co-design can help develop more empathy with research subjects and ensure that interventions are more acceptable to the users (267). The men were interviewed specifically regarding their perspectives on HPs' address of i-PAVED; however, the men requested a broad and comprehensive communication. Therefore, this pre-intervention study, involving the potential receivers of PAVED can contribute to the development of a need-driven, rather than decision-driven, intervention. The sample in **Studies II and III**, included men from a Danish municipal cardiac secondary prevention and rehabilitation programme, and the transferability of the results may be limited to men in similar contexts, for example primary care.

In **Study IV** (4), the sample size of 40 for validity testing of SA-SH-D could be considered too small; however, a sample size of >40 participants is considered to give acceptable results (268). The Cronbach's α level for the SA-SH-D was 0.67, and sufficient reliability to be used for group evaluation is recommended to be 0.70 (162). In **Study IV**, further psychometric testing with a larger sample sizes was recommended (4) as this can improve insight into the quality and applicability of a questionnaire (269). In the larger psychometric study of SA-SH-D (111 participants), Cronbach's α for the total scale was 0.84, indicating good internal consistency (243). In Study IV, a test-retest was not used for evaluating the intra-rater reliability. The reason for not using test-retest was the assumption that by answering a questionnaire concerning sexual health, the participant might start reflecting over the content of the questionnaire, and this cognitive process could influence the re-test response (4). A cognitive interview showed that students started cognitive processes and reflections

when responding to the SA-SH-D (243), and in a performed test-retest of SA-SH-D the percentage of exact agreement per item ranged from 48.6% -70.3% - and when allowing for one-point difference, it ranged from 88.2% - 100% (243). Percentages of agreement on the total scale were 59.6% and 95.2%, respectively. Some suggest that a minimum agreement of 70% is indicated as acceptable for exact agreement for ordinal scales when assessing agreement-based reliability estimates (270). In this study, the percentages of exact agreement are lower than 70. However, achieving high exact agreement can be challenging in questionnaires measuring attitudes, and simply responding to the SA-SH-D, where students are confronted with the novelty of addressing sexual health as a part of their future profession may have caused the students' attitudes to change slightly during the test period as considered in **Study IV** (4).

In **Study V** (5), SA-SH-D, a validated and reliable questionnaire was used for data collection (5). There is a risk that a student could have answered the questionnaire more than once or that a non-eligible respondent responded because the survey was distributed via an open link on the health professional students' learning platform (5). However, advantages of an online open link questionnaire are that it is simple to distribute nationwide via email, it is anonymous, the data collection can be followed, and after the data collection, data is immediately available online and ready for analysis (5).

In this project, the MRC framework was the overall inspiration in the development of the intervention PAVED, emphasising the importance of designing interventions. Whereas MRC is limited in terms of concrete guidance on how to actually do this in practice, the MRC has influenced other researchers (271), including the theoretical model enriching the MRC development phase by Bleijenberg et al. (13), which optimized the development of the complex intervention PAVED. Likewise, the TFA by Sekhon et al. (123), building on the MRC, was helpful in exploring the prospective acceptability of the component i-PAVED in this pre-intervention phase. Thus, the advantage of applying the MRC framework was the coherence and consistency in key terms and definitions. Other frameworks and co-designs might have inspired the project (267,271); however, across methods, there is an agreement of four tasks that need to be completed when designing individual-level interventions: identifying barriers, selecting intervention components, using theory, and engaging end-users (271), all of which were included in this project. In the project, the key rationale for PAVED was identified in existing evidence and theory. A level of moderate to high-intensity physical activity, 40 minutes 4 times a week, was investigated as recommended to reduce vascular ED. Potential receivers prospectively accepted health professionals' address of i-PAVED, and their perspectives gained new insight into why, what, how and which regarding health professionals' provision of the communication component i-PAVED. The future potential providers had insufficient capacity to address sexual health and a need for education in the field. The next step in developing PAVED should be competence development of current cardiac health professionals, including their perspective on providing PAVED.

CHAPTER 5. CONCLUSION

The overall aim of this PhD project was to develop the complex intervention Physical Activity to reduce Vascular ED (PAVED) for men with vascular risk factors for ED; to investigate the evidence on the level of the active component, physical activity needed to reduce vascular ED; to explore the acceptance and perspectives among men with cardiovascular diseases on health professionals' address of and communication about i-PAVED, and to investigate Danish health professional students' attitudes, competence, readiness and capacity to address sexual health.

In conclusion: the level of physical activity to reduce vascular ED is recommended as supervised exercise consisting of 40 minutes of aerobic physical activity of moderate to high intensity, 4 times a week for 6 months.

Receivers of PAVED, that is men attending municipal cardiac secondary prevention and rehabilitation, prospectively seemed to accept the communicative active component, i-PAVED provided that health professionals are professional, educated and competent in the field of sexual health. The men perceived ED as a major problem, which is tabooed and ignored by health professionals whose information, dialogue and written material about the links between lifestyle, cardiovascular diseases, ED and i-PAVED are requested by the men. Furthermore, the men preferred self-care advice on how to prevent or reduce and cope with ED, individual sessions and involvement of their partners. To meet the men's needs, the health professionals must be educated in the field of sexual health using a biopsychosocial approach including the PLISSIT-model to make ED comprehensive and manageable.

The SA-SH-D is a valid and reliable questionnaire that can be used to measure health professional students' attitudes towards working with sexual health in their future profession.

A substantial proportion of health professional students in Denmark reported positive attitudes as well as a lack of basic knowledge, competence, communication training and education in the field of addressing sexual health.

Overall, across the included studies, the findings in this PhD project have contributed to providing an evidence and needs-driven base for intervention studies for the complex intervention PAVED, together with increased understanding of the importance of educating future healthcare providers in sexual health.

CHAPTER 6. IMPLICATIONS

Overall, a successful development and implementation of PAVED can improve the quality of cardiovascular secondary prevention and rehabilitation, implicating an improved quality of life for men and their partners. This quality improvement can better men and their partners' understanding of cardiovascular risk factors, vascular ED and, thereby, their sexual function and health. If men's motivation to be physically active is positively affected by i-PAVED (as hypothesized), implementation of PAVED may also increase men's adherence to cardiovascular secondary prevention and rehabilitation guidelines and thereby their erectile function, health, cardiovascular prevention and rehabilitation, and life expectancy.

6.1. CLINICAL IMPLICATIONS

Cardiac health professionals should be involved in the further development phase of the intervention, PAVED before proceeding to the feasibility and piloting phase.

The intervention PAVED targets men; however, in Denmark, both men and women participate in cardiovascular secondary prevention and rehabilitation, and therefore the address of sexuality and sexual health should target both sexes.

Health professionals' education and competence development in the field of sexual health are prerequisites for a pilot test of i-PAVED. After careful design and piloting of the intervention, PAVED can be evaluated, implemented and disseminated in various relevant healthcare contexts, including men with cardiovascular risk factors.

6.2. GUIDELINE IMPLICATIONS

With regard to **Study I** (1) Allen stated that current guidelines regarding ED treatment do not include any specific recommendations for the content of physical activity training programmes, that this lack might explain why physical activity is rarely prescribed to patients; that in order to maximize the likelihood of treatment success, development of a treatment algorithm tailored to the mechanisms through which physical activity works as a treatment is important; and that a preliminary treatment algorithm should be developed using the current body of research on physical activity and ED (11). The findings of this project can contribute to increase the promotion of physical activity as a treatment of vascular ED, and the identified rationale, developed evidence and explored needs for PAVED should be included in national and international guidelines regarding ED and cardiovascular diseases (8,18,20,22,119,128,130,185,272-276). National clinical guidelines regarding PAVED should be developed involving patient associations such as Hjertereforeningen (the Danish Heart Foundation) in Denmark.

6.3. EDUCATIONAL IMPLICATIONS

Education in the field of sexual health in general and PAVED specifically, should be included in basic health professional programmes, for nursing, physiotherapist, occupational therapists and medicine students. Sexual health education should improve health professional students' knowledge, competences, readiness and capacity to initiate and address communication with patients regarding sexuality, ED and sexual health. Sexual health competence development to be able to provide PAVED should be developed and arranged for nurses, physiotherapists, occupational therapists, and physicians.

To further developing the complex intervention PAVED, providers of PAVED should be involved in a process that determines and defines their needs regarding competence development in the field of sexual health required to provide PAVED, in order to ensure need-driven content, development and design of their sexual health educational intervention.

6.4. PUBLIC HEALTH IMPLICATIONS

Based on the evidence on the preventive effect of physical activity on ED, inclusion of information about physical activity to prevent ED can be considered in sexual health education for students in colleges, vocational training education and teacher education as well as in public health information for the general population

6.5. RESEARC IMPLICATIONS

The findings of **Studies I, II and III** of this project can be applied in a provisional description of PAVED by use of the Template for Intervention Description and Replication (TIDieR) checklist and guide (277), and the checklist can inspire further development and design of the intervention of PAVED. The intervention Complexity Assessment Tool for Systematic Reviews (iCAT_SR) can be used as a tool to assess and categorize levels of the PAVED intervention complexity (278)

Providers of PAVED, the health professionals, should be involved in the development and design of a need-driven, tailored sexual health competence development intervention. The objective of sexual health competence development is recommended to ensure the professionals' professionalism and competences in addressing and communicating about sexuality and ED when providing PAVED. Researchers should also consider testing the effectiveness of the sexual health educational programmes (254). Inspired by the MRC (12-14), participatory design, co-design (279) and co-creation (267,280-282), future researchers should consider involvement of stakeholders – both end users/receivers and providers of PAVED – during further development, pilot testing, evaluation, implementation and dissemination of PAVED.

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APPENDICES

Appendix A. The SA-SH-D

Sundhedspersonalets holdning til at arbejde med seksuel sundhed – spørgeskemaundersøgelse

Du indbydes til at deltage i et forskningsprojekt, som har til formål at undersøge, hvordan studerende i forskellige sundhedsuddannelser ser på at arbejde med seksuel sundhed i deres fremtidige profession. Seksuel sundhed er et nyt område, som WHO fremhæver som vigtigt. Seksuel sundhed er en vigtig del af at have et godt helbred og er betydningsfuldt for menneskers livskvalitet. I denne undersøgelse defineres seksuel sundhed ifølge WHO's definition: *"Seksuel sundhed er en tilstand af fysisk, følelsesmæssig, mental og social velbefindende i forhold til egen seksualitet. Seksuel sundhed forudsætter en positiv og respektfuld tilgang til seksualitet og seksuelle forhold samt muligheden for at have behagelige og sikre seksuelle oplevelser, uden tvang, diskrimination og vold"*.

Alle besvarelser bliver anonymiseret ved databehandling.

Jeg har læst introduktionen til spørgeskemaet og er indforstået med at udfylde skemaet.

☐ Ja

Alder: _____

Vær venlig at besvare hvert af følgende spørgsmål med et kryds i et af felterne

Køn: Kvinde ☐ Mand ☐ Andet ☐

Semester: 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐

Uddannelse: Ergoterapeut ☐ Sygeplejerske ☐ Fysioterapeut ☐

Vær venlig at udfylde det følgende skema med ét kryds i ét af felterne til højre for udsagnet.

1	Jeg føler mig godt tilpas med at informere om seksuel sundhed til fremtidige patienter	Hvor godt passer udsagnet på dig?				
		Slet ikke <input type="checkbox"/>	I ringe grad <input type="checkbox"/>	I nogen grad <input type="checkbox"/>	I høj grad <input type="checkbox"/>	I meget høj grad <input type="checkbox"/>

2	Jeg føler mig godt tilpas med at indlede en samtale om seksuel sundhed med fremtidige patienter	Hvor godt passer udsagnet på dig?				
		Slet ikke <input type="checkbox"/>	I ringe grad <input type="checkbox"/>	I nogen grad <input type="checkbox"/>	I høj grad <input type="checkbox"/>	I meget høj grad <input type="checkbox"/>

3	Jeg føler mig godt tilpas med at samtale med mine fremtidige patienter om seksualitet	Hvor godt passer udsagnet på dig?				
		Slet ikke <input type="checkbox"/>	I ringe grad <input type="checkbox"/>	I nogen grad <input type="checkbox"/>	I høj grad <input type="checkbox"/>	I meget høj grad <input type="checkbox"/>

4	Jeg føler mig godt tilpas med at diskutere spørgsmål om seksuel sundhed med fremtidige patienter, uanset køn	Hvor godt passer udsagnet på dig?				
		Slet ikke <input type="checkbox"/>	I ringe grad <input type="checkbox"/>	I nogen grad <input type="checkbox"/>	I høj grad <input type="checkbox"/>	I meget høj grad <input type="checkbox"/>

5	Jeg føler mig godt tilpas med at diskutere spørgsmål om seksuel sundhed med fremtidige patienter, uanset alder	Hvor godt passer udsagnet på dig?				
		Slet ikke <input type="checkbox"/>	I ringe grad <input type="checkbox"/>	I nogen grad <input type="checkbox"/>	I høj grad <input type="checkbox"/>	I meget høj grad <input type="checkbox"/>

6	Jeg føler mig godt tilpas med at diskutere spørgsmål om seksuel sundhed med fremtidige patienter, uanset kulturel baggrund	Hvor godt passer udsagnet på dig?				
		Slet ikke	I ringe grad	I nogen grad	I høj grad	I meget høj grad
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7	Jeg føler mig godt tilpas med at diskutere spørgsmål om seksuel sundhed med fremtidige patienter, uanset seksuel orientering	Hvor godt passer udsagnet på dig?				
		Slet ikke	I ringe grad	I nogen grad	I høj grad	I meget høj grad
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8	Jeg føler mig godt tilpas med at diskutere konkrete seksuelle aktiviteter med fremtidige patienter	Hvor godt passer udsagnet på dig?				
		Slet ikke	I ringe grad	I nogen grad	I høj grad	I meget høj grad
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9	Jeg føler mig uforberedt på at samtale med fremtidige patienter om seksuel sundhed	Hvor godt passer udsagnet på dig?				
		Slet ikke	I ringe grad	I nogen grad	I høj grad	I meget høj grad
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10	Jeg tror, at jeg vil kunne føle mig forlegen hvis fremtidige patienter taler om seksuelle emner	Hvor godt passer udsagnet på dig?				
		Slet ikke	I ringe grad	I nogen grad	I høj grad	I meget høj grad
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11	Jeg tror, at fremtidige patienter kan blive forlegne, hvis jeg stiller spørgsmål omhandlende seksualitet	Hvor godt passer udsagnet på dig?				
		Slet ikke	I ringe grad	I nogen grad	I høj grad	I meget høj grad
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12	Jeg er bange for, at patienterne kan føle ubehag, hvis jeg taler om seksuelle emner	Hvor godt passer udsagnet på dig?				
		Slet ikke <input type="checkbox"/>	I ringe grad <input type="checkbox"/>	I nogen grad <input type="checkbox"/>	I høj grad <input type="checkbox"/>	I meget høj grad <input type="checkbox"/>

13	Jeg er bange for, at en samtale om seksuel sundhed kan skabe afstand mellem mig og patienterne	Hvor godt passer udsagnet på dig?				
		Slet ikke <input type="checkbox"/>	I ringe grad <input type="checkbox"/>	I nogen grad <input type="checkbox"/>	I høj grad <input type="checkbox"/>	I meget høj grad <input type="checkbox"/>

14	Jeg tror, at jeg i mit arbejde vil have for travlt til at kunne nå at håndtere seksuelle emner	Hvor godt passer udsagnet på dig?				
		Slet ikke <input type="checkbox"/>	I ringe grad <input type="checkbox"/>	I nogen grad <input type="checkbox"/>	I høj grad <input type="checkbox"/>	I meget høj grad <input type="checkbox"/>

15	Jeg vil tage mig tid til at tale om seksuelle emner med mine fremtidige patienter	Hvor godt passer udsagnet på dig?				
		Slet ikke <input type="checkbox"/>	I ringe grad <input type="checkbox"/>	I nogen grad <input type="checkbox"/>	I høj grad <input type="checkbox"/>	I meget høj grad <input type="checkbox"/>

16	Jeg er bange for, at mine fremtidige kolleger vil synes, at det er upassende, hvis jeg tager seksuelle spørgsmål op med patienterne	Hvor godt passer udsagnet på dig?				
		Slet ikke <input type="checkbox"/>	I ringe grad <input type="checkbox"/>	I nogen grad <input type="checkbox"/>	I høj grad <input type="checkbox"/>	I meget høj grad <input type="checkbox"/>

17	Jeg er bange for, at mine fremtidige kolleger vil føle sig utilpas med at håndtere spørgsmål om patienternes seksuelle sundhed	Hvor godt passer udsagnet på dig?				
		Slet ikke <input type="checkbox"/>	I ringe grad <input type="checkbox"/>	I nogen grad <input type="checkbox"/>	I høj grad <input type="checkbox"/>	I meget høj grad <input type="checkbox"/>

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18	Jeg tror, at mine fremtidige kolleger vil være modvillige til at tale om seksuelle emner	Hvor godt passer udsagnet på dig?				
		Slet ikke <input type="checkbox"/>	I ringe grad <input type="checkbox"/>	I nogen grad <input type="checkbox"/>	I høj grad <input type="checkbox"/>	I meget høj grad <input type="checkbox"/>

19	Jeg har i min uddannelse fået undervisning om seksuel sundhed	Hvor godt passer udsagnet på dig?				
		Slet ikke <input type="checkbox"/>	I ringe grad <input type="checkbox"/>	I nogen grad <input type="checkbox"/>	I høj grad <input type="checkbox"/>	I meget høj grad <input type="checkbox"/>

20	Jeg mener, at jeg som studerende har brug for at få grundlæggende kundskaber om seksuel sundhed i løbet af min uddannelse	Hvor godt passer udsagnet på dig?				
		Slet ikke <input type="checkbox"/>	I ringe grad <input type="checkbox"/>	I nogen grad <input type="checkbox"/>	I høj grad <input type="checkbox"/>	I meget høj grad <input type="checkbox"/>

21	Jeg har tilstrækkelig kompetence til at kunne tale om seksuel sundhed med mine fremtidige patienter	Hvor godt passer udsagnet på dig?				
		Slet ikke <input type="checkbox"/>	I ringe grad <input type="checkbox"/>	I nogen grad <input type="checkbox"/>	I høj grad <input type="checkbox"/>	I meget høj grad <input type="checkbox"/>

22	Jeg mener, at det er nødvendigt, at jeg i min uddannelse lærer at samtale om seksuel sundhed.	Hvor godt passer udsagnet på dig?				
		Slet ikke <input type="checkbox"/>	I ringe grad <input type="checkbox"/>	I nogen grad <input type="checkbox"/>	I høj grad <input type="checkbox"/>	I meget høj grad <input type="checkbox"/>

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