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TITLE PAGE

Study design of 'Move More': Development and feasibility of a social prescribing intervention to increase physical activity among inactive Danes

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ABSTRACT

Aim: This paper describes the design of the 'Move More' study, which aims to develop and assess the feasibility of a social prescribing intervention to increase physical activity among physically inactive Danes.

Background: Physical inactivity constitutes a public health challenge in Denmark. Social prescribing may be a promising tool to tackle physical inactivity by linking physical activity support from general practitioners with community-based activities in sports clubs, as this may help physically inactive citizens become more physically active. Given the range of stakeholders and behaviours required for social prescribing of physical activity, an intervention that harnesses this approach may constitute a complex intervention. The methods and decisions made in the stages of developing complex interventions are seldom reported. The present study enables us to describe how co-creation can be used in a pragmatic development process for a complex intervention that considers the needs of stakeholders and the conditions of the delivery context.

Methods: The study is based on the core elements of the development and feasibility phases of the Medical Research Council Framework for Developing and Evaluating Complex Interventions. Additionally, it is informed by a framework for the co-creation and prototyping of public health interventions drawing from a scoping review, stakeholder consultations and co-creation workshops. Ultimately, a feasibility study will be conducted to refine the programme theory by introducing the proposed intervention in case studies.

Perspectives: The study will result in a prototype intervention manual and recommendations for implementation of an adapted social prescribing intervention targeting physical inactivity in Denmark.

Key words: Social Prescribing, Exercise, Physical Activity, General Practice, Complex Interventions, Referral and Consultation, Community Health Services, Health Promotion, Co-creation

Word count: 3947

MAIN TEXT

Introduction

When developing public health improvement interventions, it is important to consider the complexities of the public health problem being targeted and the context in which the intervention will exist in order to improve the chances of successful future implementation[1]. If not developed carefully, interventions risk being ineffective and research resources being wasted[2-4]. Although the importance of systematic development processes of interventions is widely acknowledged[5], the methods and decisions made in the early stages are seldom explicitly reported[3]. Hence, intervention development is sometimes referred to as the 'black box' of intervention research[2]. Several guides for developing public health interventions have been published to enhance the design phase of interventions before studying their implementation and effectiveness[3-5]. In the recent update to the Medical Research Council (MRC) Framework for developing and evaluating complex interventions[1], it is recommended to consider a set of core elements when developing complex interventions, including context, programme theory, engaging stakeholders, identifying key uncertainties, refining the intervention, and economic considerations. The focus on these core elements stresses the importance of a carefully prepared development process that is aligned with key contextual considerations including the views and experiences of the intended recipients and implementers and the setting in which the intervention will be delivered.

Informed by the MRC framework, the present paper describes the design of the 'Move More' study, which aims at developing a social prescribing (SP) intervention to increase physical activity among physically inactive Danes.

Background: The 'Move More' study

Population-based data reveal that 58,1% of Danish adults aged 16-75 years do not comply with the WHO minimum recommended levels of physical activity [6], suggesting that adults should do at least 150–300 minutes of moderate-intensity physical activity pr. week; or at least 75–150 minutes of vigorous-intensity aerobic physical activity pr. week. . Furthermore, physical inactivity is more common among people with lower educational levels and people with chronic disease and/or multimorbidity[7]. Consequently, physical inactivity is a public health concern in Denmark with large socioeconomic and human losses[8], constituting a barrier to equity in health.

An approach that has shown promise in tackling physical inactivity is a collaborative community-setting approach[9] which links physically inactive citizens and the stakeholders who help Danes to establish and maintain PA[10]. In this regard, general practitioners (GPs) have a key potential at a community level as they are consulted by approximately 85% of the Danish population over a one-year period[11]. A survey by Joergensen et al. found that 95% of Danish GPs report to give advice on PA at least weekly in consultations with citizens. However, the GPs often have little knowledge of existing community-based PA options, and many are challenged by limited time and lack of referral opportunities[12]. This suggests a need for strategies to support GPs in providing more specific PA counselling.

Danish sports clubs (SCs) offer many activities that could provide referral opportunities. With more than 11,000 national clubs, Danish SCs have a key potential to prevent physical inactivity. However, research suggests that lack of tailored recruitment strategies and shortage of coaching skills (to support physically inactive individuals)[13-15] are key challenges in SCs aiming to engage physically inactive groups, such as individuals with chronic diseases and/or multimorbidity. Hence, detailed knowledge is called for on the 'readiness' of Danish SCs to actively integrate physically inactive citizens.

A systematic inter-sectoral collaboration between Danish GPs and SCs may provide an attractive community setting to support physically inactive citizens in becoming physically active. As a mediating tool, social prescribing may enable GPs to refer citizens to non-clinical health-promoting services in the local community, which may be beneficial to reduce physical inactivity in Denmark. social prescribing is a relatively new approach, which has gained considerable attention in a number of European countries, especially in the UK[16], as an emerging strategy to tackle health inequities through collaboration between primary healthcare and third sector organisations. As an instrumental tool, social prescribing may have the potential to create a link between GPs' PA counselling and community-based activities in Danish SCs.

Method

Design

The 'Move More' study will use a comprehensive approach to intervention development following the development and feasibility phases described in the MRC framework. Research questions related to the six core elements of the MRC Framework, e.g., '*How does the intervention interact with its context?*' and '*What are the key uncertainties?*'[1], will be considered, answered, and revisited throughout the 'Move More' study. This will be combined with an additional three-stage co-creation framework (Figure 1) inspired by Hawkins et al.[17]. The study is designed to develop a theoretical understanding of the likely process of change, informed by scientific literature and theory, new primary research, and the integration of knowledge from key stakeholders, to facilitate the future implementation of social prescribing for physical activity in Denmark.

[Insert Figure 1]

Co-creation

Many studies suggest that a suitable framework for developing a complex intervention should include co-creation processes that involve stakeholders and citizens in all phases of an intervention [4, 18]. In the present study, co-creation will be used as a suitable approach to develop an social prescribing intervention adapted to a Danish setting through the use of the core elements of the MRC Framework. The study builds on the definition of co-creation by Leask et al. (2019) as a "*collaborative public health intervention development by academics working alongside other stakeholders*". Thus, the 'Move More' study will include health professionals in general practice, stakeholders in SCs, and citizens who are physically inactive.

Empirically, the concept of co-creation is blurred, and many terms are used covering various overlapping concepts, such as co-production, co-designing, and co-innovation[19]. However, in this study, we have chosen to use the concept of co-creation since we do *not* intend to produce and deliver a pre-defined model of social prescribing. Rather, in our understanding, the process of co-creation aims to engage stakeholders in an interactive and collaborative creation and formulation of new innovative ideas to enhance the public value[19, 20] of social prescribing in a Danish setting. Furthermore, it is the intention for all stakeholders to have equal opportunities for input alongside the research team.

Additionally, our rationale for involving key stakeholders from the start of the development phase is to identify priorities, clarify links and contextual aspects of the problem, and identify 'active ingredients' that are likely to make a difference in the implementation context[3, 4]. Furthermore, including the knowledge and views of key-stakeholders who are 'experts by experience' is essential to create favourable circumstances for developing an intervention that is accepted by stakeholders and is feasible to implement in practice in the context of Danish primary care[1, 17]. In the 'Move More' study, co-creation will mainly take the form of collaborative workshops with multi-sectoral stakeholders to develop a shared sense of ownership[17].

Intervention

Social prescribing of PA is one of the most widely used models of social prescribing[16]. It is sometimes referred to as 'exercise referral schemes'. Various social prescribing approaches may be utilized to support the community referral of physically inactive, vulnerable target groups, such as people with chronic diseases and/or multimorbidity. A common resource in social prescribing is a *link worker*, who provides emotional support and identifies relevant community-based activities aligned with the individual citizen's needs and requests. The link worker supports the community referral from general practice. Intensive support provided by link workers seems to be a more successful model of social prescribing than "simply signposting", such as using leaflets to inform about community activities. Furthermore, research suggests that the accessibility of activities in terms of the required equipment, the costs of attending the activity, and the physical proximity to social prescribing activities is important for the citizens' participation and engagement[16]. Moreover, flexible activities, where citizens can participate on a drop-in basis according to their fluctuating health status, also seem to assist the referral to social prescribingactivities[21]. The citizens' adherence to the social prescribing activities seems to be influenced by skilled and knowledgeable activity leaders and by participants' perceived positive changes in their health condition and symptoms[16]. Yet, the main reasons for dropping out seem to be limited choice of accessible activities or lack of suitable activities according to the citizens' functional level[16]. Thus, in this concern, SCs offering a wide range of activities that are readily accessible to beginners may be of particular interest.

To illustrate how the intervention is proposed to work, an initial logic model has been developed[22] (Figure 2). In 'Move More', we depict programme theories in the diagrammatic form of logic models to clarify the pathway between program objectives, inputs, activities, and

intended outcomes and to identify key uncertainties[1]. Throughout stages 1-3, the development and refinement of logic models will follow the typology by Mills et al., starting from basic 'Type 1' logic models to more context-sensitive 'Type 4' logic models [22], which can be adapted to different settings. In addition, the ongoing development of logic models provides specific talking points for stakeholders during the co-creation workshops to search for consensus[22]. Relevant theoretical explanations to inform and explain the chains of the logic models will also be identified and included[3, 4], such as motivation theories, for instance self-determination theory[23].

[Insert Figure 2]

Target population

The main target population of our suggested social prescribing intervention for PA will be Danish adults (aged 18+) and elders (aged 65+) who do not comply with the WHO-recommended PA levels and who are not living in residential or sheltered accommodation. Specifically, the intervention aims to target patients in primary care, who are advised by their GP to become more physically active in light of their current health. A recent survey among 52 Danish GPs suggested that social prescribing to increase PA could be useful for patients with metabolic syndrome, diabetes, or obesity, closely followed by patients with cardiovascular diseases, low back pain, arthrosis, and chronic obstructive pulmonary disease, whereas the patient groups rated as the least suited to receive an social prescribing intervention were patients with eating disorder or migraine[24]. An in-depth interview study among Danish GPs found that SP may especially benefit vulnerable patients with mental or chronical illness and few resources who need a helping hand to identify and participate in community-based physical activities [12]. Overall, the target population for an social prescribing intervention towards PA

has been identified to have a medical need to become more physically active, preferably in a local community setting.

Data sources

Stage 1: Evidence review and stakeholder consultations

During Stage 1, a scoping review and stakeholder consultations will explore the nature of the problem of physical inactivity (in the context where the intervention is intended to take place to inform the development of program theories).

A scoping review will be conducted to summarise and synthesise research findings and grey literature on social prescribing or similar initiatives towards community-based PA targeting physically inactive adults or elders. To systematize our review and ensure transparent reporting, the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist[25] will be followed. Search strings will be developed for the following databases: PubMed, Embase and SPORTDiscus. Besides electronic databases, information will be sought from relevant Danish organisations, such as reports from the Danish Health Authority, Sports Confederation of Denmark (DIF), and the Danish Gymnastics and Sports Association (DGI). To obtain knowledge on the most recent literature, we will consider only studies published from 2000 onwards (in English or Danish). To exclude studies and methods that are not generalizable to the Danish setting, eligible studies must examine initiatives in Scandinavian or Western countries (Europe, North America, and Australia). Furthermore, four expert interviews with respondents working with recruitment towards community-based PA will be conducted to collect insights that are not publicly available in scientific or grey literature. Overall, the scoping review aims to inform the initial program theory of the intervention by drawing on existing interventions and obtaining an understanding of the research base that underpins the proposed intervention components[3, 4].

Furthermore, our scoping review is intended to clarify and specify research gaps and key uncertainties to be explored in the following stakeholder consultations[4].

The stakeholder consultations will include healthcare professionals in general practice and staff/volunteers in SCs who organize activities to which the target population can be referred. The overall aim of the stakeholder consultations is threefold: to gather perspectives and preferences from multiple stakeholders regarding issues related to promoting PA among physically inactive citizens, to understand the context and clarify the existing procedures and capacities in both general practice and SCs, and to identify ideas for appropriate social prescribinginterventions[3, 17]. As different ways of involvement are needed for different types of stakeholders[4], the stakeholder consultations will take form as multi-method case studies in SCs, whereas focus group interviews will be conducted in general practice.

Case studies of SCs will be interpreted in relation to views and potential barriers towards enhanced integration of inactive citizens through social prescribing. Hence, multiple case studies will be used to learn about the values and the environment in Danish SCs in relation to social prescribing. The cases will be selected in collaboration with the umbrella organization of Danish sports clubs, DGI, to ensure maximum variation, i.e. inclusion of SCs of differing size (number of members), location (urban or rural) organization type (employees or volunteers), and willingness to initiate new activities targeting inactive citizens. To obtain this information, an initial survey will be sent to approximately 700 SCs in the Central Denmark Region, which are considered to be representative of Danish SCs. The initial survey will inform the selection and recruitment of cases. The case studies will include three components: i) a document analysis of publicly available documents from each involved SC, ii) observations of board meetings and training sessions, and iii) focus group interviews for each case. Overall, the multiple case studies will provide new insights into the current attitudes, settings, and

competencies in Danish SCs with a view to enhanced integration of inactive citizens by social prescribing.

To investigate perspectives on social prescribing in general practice, 10-12 stakeholders, such as GPs and local practice consultants, who already operate in the field of inter-sectoral collaboration in general practice, will be recruited for two focus group interviews. Selection of informants will ensure diversity in gender, age, location of practice (urban or rural), and clinic type (solo or partnership practice). The focus group interviews aim to elicit views on the current practice of PA counselling and how an social prescribing intervention could be organised.

The MOVE more study intend selected informants to partake through both stage 1 and stage 2, to increase learning outcome and alignment. The selected informants appearing both stages, are chosen with diversity in mind as seen with our focus groups. In addition, we hope that new informants can be recruited whose contributions can further stimulate learning. Finally, we hope that we can recruit representatives of the target group as well.

Stage 2: Co-creation workshops

Selected informants from stage 1 will constitute an 'intervention development group' to co-create an adapted model of social prescribing for community-based PA. Data from stage 1 will be used to inform the selection of group members, ensuring a range of views, knowledge, and experience represented. In addition, the co-creation workshops intend to foster a shared sense of ownership among key stakeholders[17] from general practice and SCs and ensure clear roles and responsibilities. Initial programme theories will be refined at two co-creation workshops and the working draft of logic models will be open to change and inputs throughout the development phase[4]. The workshop process will be inspired by the community-based system dynamics facilitation technique of group model building (GMB)[9, 26]. Through the use of GMB, a system thinking approach will be applied to take into account the complexity of physical

inactivity. Informed by the findings from stage 1, stakeholders will be involved in a process of using system dynamics by building 'casual loop diagrams' (CLD), which will allow them to share mental models of causes and effects[26] of physical inactivity. Finally, after iterative processes comprising loops of feedback, discussions, and agreement[17], a developed system map will inform the refinement of program theories. Hence, the product of stage 2 is an optimised prototype of how a Danish model of social prescribing towards community-based exercise could be delivered when ready for testing in a feasibility study (stage 3). The literature review will continue throughout stage 2 to further qualify the programme theories and to address uncertainties arising in the workshops, e.g., regarding new intervention components[4].

Stage 3: Feasibility testing and prototyping

To test the delivery of the prototype social prescribing intervention, a feasibility study will be conducted. Based on the co-created program theories, an adapted model of social prescribing will be introduced into the case studies each comprising at least one general practice and one SC in the same local area. A six-month feasibility study will follow, where GPs can refer physically inactive citizens to community-based activities in SCs. Based on previously research by Christensen & Nielsen[24], subgroups of patients have been found more applicable for social prescribing interventions, which will form part of our exclusion-criteria for GPs not to include physically inactive patients. Furthermore stakeholder consultations in stage 1 and co-creation workshops at stage 2, will also emphasize who should get a reference to social prescribing interventions in the feasibility study.

The data collection will be based on monitoring of the number of referrals, observations of activities, interviews with instructors, link workers and GPs, and focus group interviews with participants engaging in the offered activities. The Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework[27] will be applied to guide the data

collection and to identify facilitators and barriers for successful implementation of a Danish social prescribing intervention. The feasibility study aims to provide essential empirical knowledge of how the recommendations of an social prescribing intervention can be translated and adapted into the implementation context [3].

Finally, information collected from all three stages will be synthesized by the authors to prototype programme theories and final recommendations. The Template for Intervention Description and Replication (TIDieR) guideline[28] will be followed to ensure detailed description of the intervention, and strategies for upscaling and transferring the intervention across settings will be considered[18]. Table 1 summarizes the data collection activities and the objectives for stages 1-3.

[Insert Table 1]

Data analysis

The data analysis will run through all three stages to ensure that outcomes can feed into the next stage. Audio recordings of interviews and focus group interviews will be transcribed verbatim and analysed with thematic coding in NVivo software. The coding will be conducted in six steps [29]: i) familiarizing with the depth and breadth of data content through initial reading, re-readings and searching for patterns, ii) generating initial codes by organizing data into meaningful groups, iii) searching for themes by combing different codes to form overarching themes, iv) reviewing themes and refining them into a 'thematic map, v) defining and naming each theme, and vi) writing up the outcomes of the thematic analysis across the generated themes[29]. Field notes from informal consultations and observations will be collated with the outcomes from the thematic analysis to identify similarities and differences across the collection of data[17].

Discussion

By combing the core elements of the MRC Framework[1] with the step-by-step guide for co-creation by Hawkins et al.[17], the 'Move More' study suggests how a systematic, transparent, and pragmatic intervention development process can be designed. Although the steps from the development phase to the feasibility phase is described as a linear progress in our study, this overlap is expected to be an iterative process[3]. In practice, findings from the feasibility phase may identify significant key uncertainties and knowledge gaps, which must be addressed. Hence, the development and refinement of intervention content is open to continuous change during the feasibility phase and the evaluation and implementation phases, as new knowledge is revealed[1, 4].

During the feasibility phase, the social prescribing intervention will be tested in urban and rural areas of Denmark, whereas the participating cases from general practices and SCs will have different delivery contexts. Hence, the test and refinement of the programme theory are based on diverse feasibility studies, and the results of the 'Move More' study are thus expected to be relevant beyond the participating cases[30]. Furthermore, we consider the perspectives and resources of key stakeholders when developing the intervention, which is expected to maximize acceptability and ensure favourable conditions for planning future implementation. Likewise, the 'Move More' study may inform the selection of appropriate outcome measures in potential future randomized controlled trials (MRC Framework, phase 3)[1].

It may be challenging to contextualize an social prescribing intervention to a Scandinavian setting since the concept of social prescribing is primarily informed by interventions conducted in the UK. Consequently, our intention is *not* to duplicate or produce a pre-defined model of social prescribing. Rather, the international concept of social prescribing will inspire the intervention content at a general level, which will be adapted to a Scandinavian delivery context through co-creation.

There are different ways of using co-creation in intervention development. In the 'Move More' study, we will use a pragmatic step-by-step guide[17] to involve multiple stakeholders in different ways, including case studies, focus group interviews, and co-creation workshops. It is unknown which specific approaches of co-creation are most appropriate, and whether generating more data and inputs from multiple stakeholders in intervention development produce more effective interventions and less research waste[2]. However, by following systematic guidelines for developing public health interventions and the core elements of the MRC framework as guiding principles[1, 17], the 'Move More' study proposes a model for combining different approaches of co-creation with new primary research, scientific literature, and theory that may identify and address key uncertainties in intervention development.

Potential of the study

The 'Move More' study will be the first step towards a Danish model of social prescribing targeting the increasing public health challenge of physical inactivity. The study will provide a knowledge base on community referrals by linking PA support from GPs with specific community-based activities in local sports clubs. Ultimately, the ambition is to develop and evaluate a GP-anchored social prescribing intervention to assist and support physically inactive Danes in becoming physically active in their local community. The findings of the current study are expected to provide practice-relevant recommendations for those involved in general practice and in sports clubs for the benefit of physically inactive Danes.

Contributors: The first draft of the paper was written by LGR and KR. All the authors revised the manuscript, contributed, and approved the final manuscript before submission. LGR is the principal investigator of the 'Move More' study and developed the project under supervision from PK, KR, RON, and JH. PK is research director at the Research Unit for General Practice in Aarhus and provided in-depth knowledge of the involvement of GPs in the development of

the project. RON contributed to the design of the study, while KR and JH provided their expertise in intervention development and co-creation.

Declaration of conflicting interests: No competing interests.

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Ethical approval: This study will be conducted in accordance with the Helsinki Declaration and the General Data Protection Regulation of the European Union. The study will be registered in the Record of Processing Activities at the Research Unit for General Practice, Aarhus. Written consent will be collected from all informants. We will apply to the Committee on Health Research Ethics in the Central Denmark Region for approval of the study.

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FIGURE 1

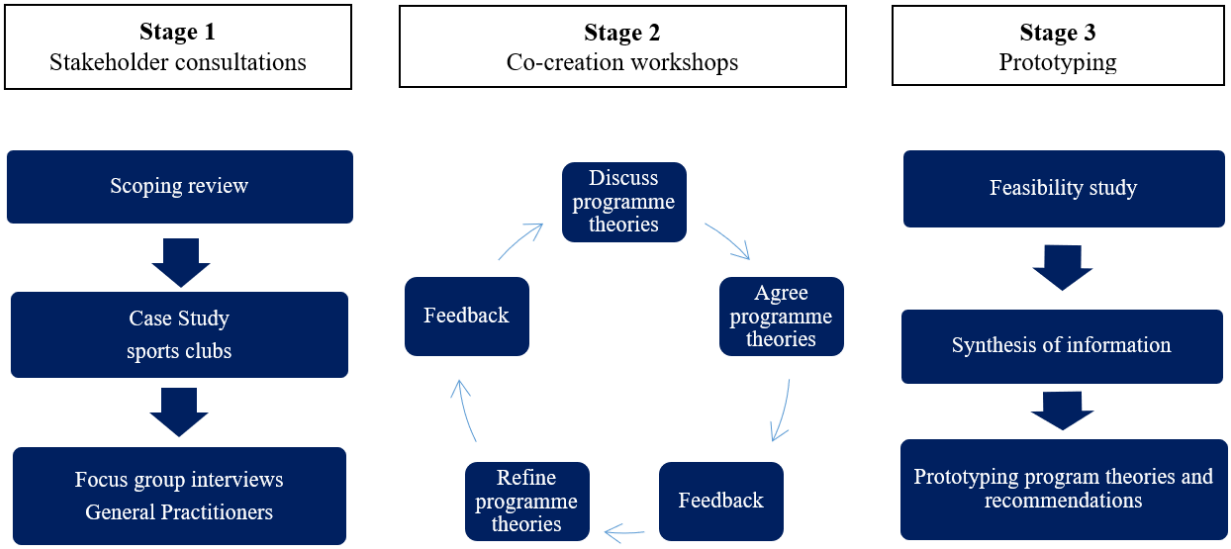

Figure 1. Framework for intervention development using co-creation and prototyping of program theories adapted from: Hawkins, J., et al., *Development of a framework for the co-production and prototyping of public health interventions.* BMC Public Health, 2017. 17(1): p. 1-11.

FIGURE 2

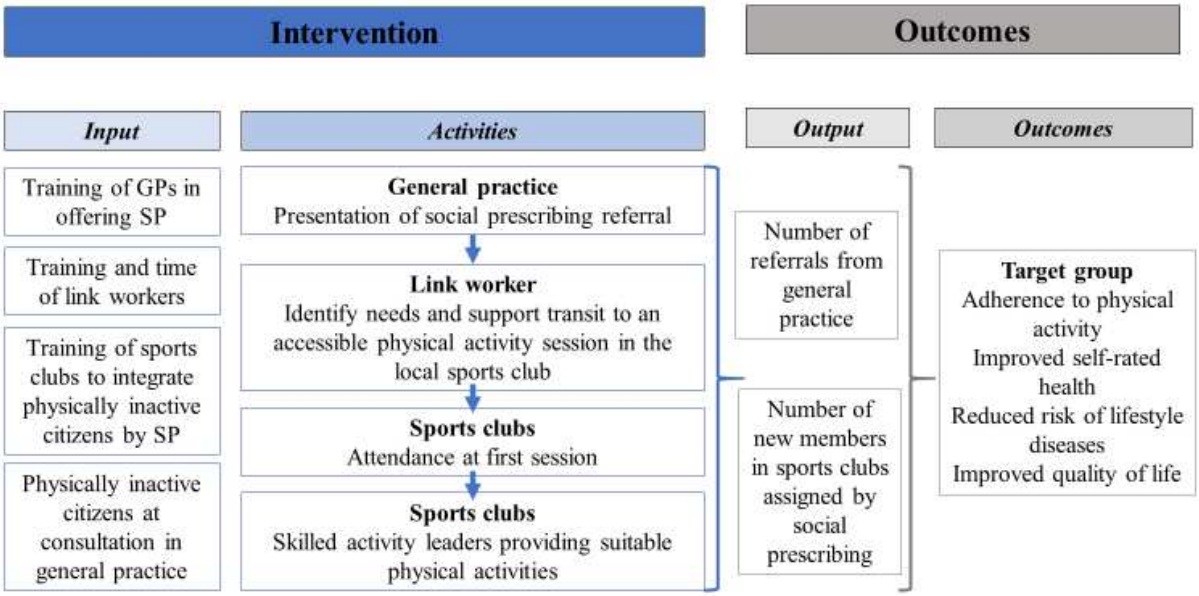

Figure 2. Initial example of a basic logic model of a SP intervention towards community-based physical activity

TABLE 1

Activity	Objectives
Stage 1: Evidence review and stakeholder consultations	
1) Scoping review 2) Case studies in sports clubs 3) Focus group interviews in general practice	1) To summarize and synthesize research findings and grey literature on SP or similar initiatives provided by healthcare professionals in general practice towards community-based physical activity targeting physically inactive adults (aged 18+) residing in Western countries 2) To provide insights into current attitudes, settings, and competencies in Danish sports clubs with a view to enhanced integration of physically inactive citizens based on SP 3) To explore perspectives regarding SP in general practice and GPs' views on how to link their current counselling on physical activity with relevant activities in community-based sports clubs
Stage 2: Co-creation workshops	
1) Two GMB-based workshops in the intervention development group	1) To explore ideas about intervention content, to develop through co-creation an adapted model of a SP intervention targeting physical inactivity, and to promote acceptability of intervention content among key stakeholders
Stage 3: Feasibility testing and prototyping	
1) Feasibility study 2) Prototyping	1) To empirically test the delivery of intervention content in practice, and to identify facilitators and barriers for reach, effectiveness, adoption, implementation, and maintenance of developed intervention content 2) To prototype intervention manual and recommendations for future implementation of an adapted SP intervention targeting physical inactivity in Denmark

Table 1. Activities and objectives from application of the three-stage framework for co-creation and prototyping of the 'Move More' study.