

The CoroPrevention-SDM Approach: A Technology-supported Shared Decision Making Approach for a Comprehensive Secondary Prevention Program for Cardiac Patients

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Abstract: After a cardiac event, secondary prevention is recommended to foster recovery and reduce the risk of recurrent events. European guidelines and EAPC position statements on prevention of cardiovascular diseases recommend a holistic approach that actively engages patients by using shared decision making (SDM). It has been demonstrated that telerehabilitation can be a feasible and effective add-on or alternative compared to conventional in-hospital secondary prevention. However, till date, there is no eHealth solution that offers a holistic approach for secondary prevention that includes SDM. In this paper, we present the CoroPrevention-SDM approach, a technology-supported shared decision making approach for a comprehensive secondary prevention program for cardiac patients. The CoroPrevention Tool Suite consists of three applications that support patients and caregivers in following this approach: 1) a caregiver dashboard that includes decision support systems and supports SDM, 2) a patient mobile application that supports patients in making behaviour changes in their daily life, and 3) an extended ePRO application that collects patient reported outcomes and patient preferences. In a formative usability study, we assessed patients' and caregivers' opinion about our approach. The study indicated that both are willing to use our proposed approach to collaboratively set behavioural goals during SDM encounters.

1 INTRODUCTION

Cardiovascular diseases are world's leading cause of death, accounting for an estimated 17.9 million deaths globally in 2019 (World Health Organization, 2021). After a cardiac incident, patients typically enrol in cardiac rehabilitation as a secondary prevention to foster recovery and reduce their risk of recurrent events (Ambrosetti et al., 2021). In this paper, we focus on two interrelated needs for a guideline-based secondary prevention program, namely its holistic perspective and integration of shared decision making. Furthermore, we elaborate on our technology-

supported shared decision making approach in the CoroPrevention project, a large-scale H2020 funded project on secondary prevention for high-risk patients. In this section, we consider the state of the art for the two identified needs and raise ideas to move beyond the currently implemented clinical practices.

1.1 The Need for a Holistic Approach

1.1.1 State of the Art

European guidelines and EAPC position statements (Ambrosetti et al., 2021; Visseren et al., 2021) rec-

ommend that a comprehensive, secondary prevention program includes the following key components: parameter monitoring, education, medication, physical activity, nutrition, smoking cessation, and stress management. For each of these key components, eHealth solutions have been developed and are even commercially available. Numerous apps are available in smartphone's app stores that enable users to set medication reminders, measure their health parameters, track their physical activity, record their nutrition intake, perform stress relief exercises, or offer smoking cessation support. However, the main disadvantages of these applications are twofold: 1) most of these applications are not tailored to the risk profile of a cardiac patient, and 2) to follow a comprehensive, secondary prevention program, the patient has to use several different applications. Using multiple applications can result in a higher cognitive burden and interference of (or even conflicting) advice offered by different applications.

In scientific literature, numerous studies were published that evaluated eHealth interventions for secondary prevention of cardiovascular diseases (Jin et al., 2019; Brørs et al., 2019). A review performed by Brørs et al. (Brørs et al., 2019) concluded that the majority of studies included two or three secondary prevention components, of which education was employed in 21 out of the 24 included studies. To the best of our knowledge, there is no eHealth solution that fully supports a comprehensive, secondary prevention program, including all key components as defined by Ambrosetti et al. (Ambrosetti et al., 2021) and that was subject to extensive evaluation on medical effectiveness and user experience.

1.1.2 Looking Beyond the State of the Art

When working on risk factor reduction to prevent recurrent cardiovascular events, the main parameters to control are blood pressure, weight, cholesterol, and glucose levels. For each of these parameters, a target value can be defined (in line with the European guidelines and EAPC position statements (Ambrosetti et al., 2021; Visseren et al., 2021)) and an outcome goal can be set (i.e. respectively lowering blood pressure, healthy weight, lowering cholesterol, and diabetes management). To improve a parameter value and achieve the associated outcome goal, different strategies can be followed. For example, a *healthy weight* can be achieved by increasing physical activity, eating healthier, or a combination of both. It is important that patients understand how they can work on an outcome goal. Setting the goal of *losing weight until your body mass index (BMI) is below 25* is too abstract for a patient. In the context of be-

haviour change, people need to set actionable goals that are directly linked to behaviours over which they have direct control (Medynskiy et al., 2011). Therefore, we suggest that in a rehabilitation program the outcome goals for secondary prevention should be linked to behavioural goals. The following five behavioural goals should be considered when aiming at a healthy lifestyle to prevent recurrent cardiac events: medication adherence, start moving, healthy nutrition, smoke-free living, and stress relief. For each of these behavioural goals, specific, short-term goals should be set (Medynskiy et al., 2011). After defining the behavioural goals for the upcoming period, it is equally important that follow-up is done and that feedback is provided on the progress towards the behavioural goals (Scobbie et al., 2011). Therefore, it is essential that patients can *monitor their parameters* and caregivers can remotely follow up on these reported values.

1.2 The Need for Shared Decision Making

1.2.1 State of the Art

From a clinical point of view, patients should reduce their cardiovascular disease (CVD) risk as soon as possible, as much as possible. This would require optimizing all outcome goals at the same time, and thus working on multiple behavioural goals simultaneously. After a cardiac incident, some patients want to drastically change their life and are eager to work on multiple or even all behavioural goals at the same time. However, this is not advised, since some behaviour changes oppose each other (e.g. smoking cessation and losing weight) which results in disillusionment for the patient. Furthermore, working on multiple behaviour changes simultaneously is not feasible for everyone. For those patients for whom a drastic approach is not feasible, a more gradual approach in which they target one behaviour change at a time works better. In such cases, it has to be decided which behavioural goal is targeted first. There is evidence that some factors (which can be linked to behaviour changes) have a bigger effect on CVD risk than others (SCORE2 working group and ESC Cardiovascular risk collaboration, 2021; SCORE2-OP working group and ESC Cardiovascular risk collaboration, 2021). However, if the patient is not willing or able to work on the behaviour change, it will be almost impossible to achieve the desired effects. Moreover, there are patients for whom it will be difficult or even impossible to tackle a certain risk factor. E.g., for a person with severe rheumatism, it will be very challenging to

achieve the exercise targets and it is better to focus on reducing the other CVD risk factors.

For this type of situations, where there is no clear best choice and the decision has to be made by balancing the pros and cons of different options (i.e. the behaviour changes), it is recommended to use *shared decision making* (Wennberg et al., 2003). Moreover, shared decision making is at the core of patient-centered care and the European Society of Cardiology also acknowledges that patient engagement (in clinical decision making) is needed to improve cardiovascular care (Graham et al., 2017; Institute of Medicine, 2001). Shared decision making (SDM) combines the patient's preferences, values, goals, and context with the clinical evidence and caregivers' expertise to make an informed decision (Kon, 2010; Stiggelbout et al., 2012), i.e. in this case which behavioural goal(s) the patient will work on first. When making this decision, the risk reduction of the different behaviour changes should be balanced with the patient's motivation to work on these behaviour changes. We propose to use a digital decision aid or SDM tool in a shared decision making encounter with the patient, to support a dialogue about the balancing exercise between the patient's motivation for behaviour change and necessary health risk reduction. Decision aids are tools that support patients and caregivers in SDM by making the decision explicit, offering information about the available options (and their advantages and disadvantages), and assisting in clarifying congruence between personal preferences/values and the decision at hand (Stacey et al., 2017).

To actively participate in shared decision making and become the manager of their own disease, patients need to understand their condition and their own preferences (Joseph-Williams et al., 2014). Therefore, *education* is an essential component when considering shared decision making in the context of secondary prevention. This education can be delivered by caregivers during the encounters using a SDM tool, but also patients can learn on their own using digital resources such as articles, videos, and infographics (Sankaran et al., 2018).

1.2.2 Looking Beyond the State of the Art

Recently, Bonneux et al. (Bonneux et al., 2019) proposed three levels of decision-making in cardiac rehabilitation (CR):

Level 1 The CR program: the key components to include and when they get the patient's focus

Level 2 The key components of the CR program: the details of the included components

Level 3 The actions for the key components: the de-

tails of what the patient can do to implement the lifestyle changes in daily life

Cardiac rehabilitation can be considered as a tool for secondary prevention of cardiovascular disease (Mampuya, 2012). Therefore, we believe that these three decision-making levels can be utilized in the context of secondary prevention of CVD as well. Furthermore, Bonneux et al. (Bonneux et al., 2019) made a categorization of different tools that can support patients and caregivers at different points in time in following a SDM approach for these three levels of decision-making.

Inspired by patients' and caregivers' need for a holistic approach and shared decision making in the context of secondary prevention of cardiovascular diseases, we developed the CoroPrevention-SDM approach. In Section 2, we describe patients' and caregivers' requirements for tools supporting SDM for a comprehensive secondary prevention program. In Section 3 and Section 4, we present our CoroPrevention-SDM approach and highlight how the digital support that was realised in CoroPrevention fulfills patients' and caregivers' needs.

2 PATIENTS' AND CAREGIVERS' REQUIREMENTS FOR SHARED DECISION MAKING TOOLS

To support patients and caregivers in shared decision making for the behavioural goals of a secondary prevention program, the approach of Bonneux et al. (Bonneux et al., 2019) can be adapted. Whereas guidance of the patient is necessary throughout the secondary prevention program, shared decision making is often facilitated in a discrete way, in a number of (physical) shared decision making encounters. When looking at a single SDM encounter, we can define three points in time where digital tools can support caregivers and patients in shared decision making:

1. Preceding to the SDM encounter
2. During the SDM encounter
3. After the SDM encounter

For these three moments in time, we describe in the next sections the goals and needs for both patients and caregivers regarding support for shared decision making.

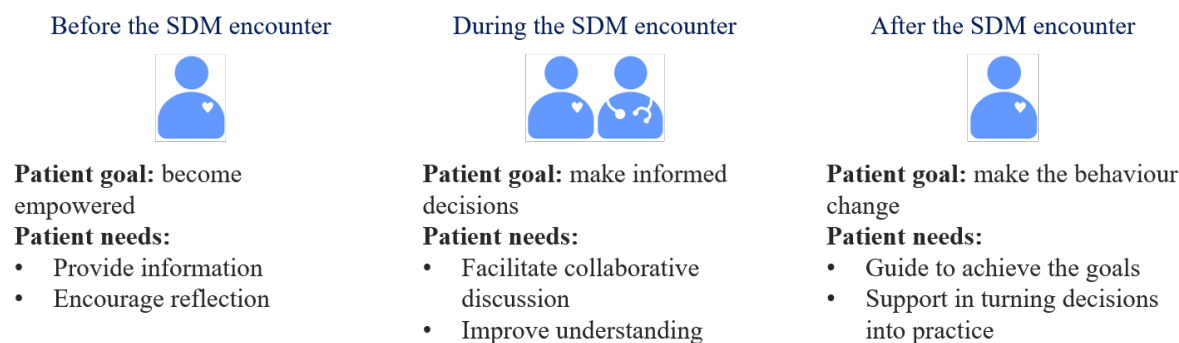


Figure 1: The patient’s goals and needs preceding to, during, and after the SDM encounter.

2.1 The Patient’s Perspective

From the patient’s perspective, the aim is to increase self-management of the disease and therefore become an active participant in the SDM process. This leads to a process that balances patient and caregiver decisions regarding the rehabilitation approach. The patient’s goals and needs that can be supported by digital tools are depicted in Figure 1. **Preceding to a SDM encounter**, digital tools can support patients in becoming informed about what will happen during the encounter. In this regard, patients should think about their preference to be involved in the decision-making process e.g. do they want to take the decision, make a shared decision, or leave the decision to the caregiver. Furthermore, digital tools can support patients in reflecting on their current status, gaining insight into their progress over the last months and into the next possible steps. Referring back to the above mentioned two aims for the patient, information and reflection, we activate and empower the patient to become active participants in the SDM consultation. **During the SDM encounter**, digital tools can support patients in improving their understanding, reflecting on past behaviour, stating their preferences, and understanding what actions should be taken. The desired result is that the patient can make an informed decision together with the caregiver during the SDM consultation and is motivated to work on the agreed behaviour changes. **After the SDM encounter**, mobile eHealth applications can support patients in making the agreed behaviour changes at home. These applications can provide patients guidance in how to achieve the behavioural goals and how to bring the decisions that were made during the encounter into practice in their daily life. There will be moments when the patient has a setback. At those moments, the tools can support the patient to feel comfortable while getting back on track. However, it is important to note that the tools cannot replace the support of the caregiver but are rather facilitating the caregiver in this role. In the

next section, we discuss how tools can support caregivers in achieving their goals.

2.2 The Caregiver’s Perspective

From the caregiver’s perspective, the aim is to make guideline-based recommendations for the patient’s treatment, to support the patient in making behaviour changes, and to follow up on the patient’s progress for a healthy lifestyle. Similarly as patients, caregivers have different goals and needs that can be supported by digital tools at different points in time (Figure 2). **Preceding to the SDM encounter**, caregivers can use digital tools to prepare themselves for the upcoming appointment, so they can make (together with the patient) well-informed decisions during the encounter. Digital tools can support caregivers in reviewing the patient’s evolution since last consultation and pending goals. In addition, decision support systems can support caregivers in preparing for prescribing guideline-based care to their patients. **During the SDM encounter**, a digital tool can support the caregiver in discussing the outcome goals that are needed from a clinical point of view (i.e. transferring knowledge to the patient) and collaboratively setting behavioural goals that are in line with the clinical evidence and the patient’s preferences (i.e. facilitating collaborative discussion and motivating the patient). The desired result is that the patient can make an informed decision together with the caregiver during the SDM consultation and that the patient is motivated to make the agreed behaviour changes. **Between SDM encounters**, caregivers want to follow up on their patients’ progress. However, there is only limited time available for this follow-up. Therefore, digital tools, such as dashboard visualizations and alerts, can support caregivers in following up on the patient’s progress. Digital tools can alert the caregiver when the patient deviates from the agreed goals and action plans, so the caregiver can contact the patient or take this into account during the next SDM encounter. At those mo-

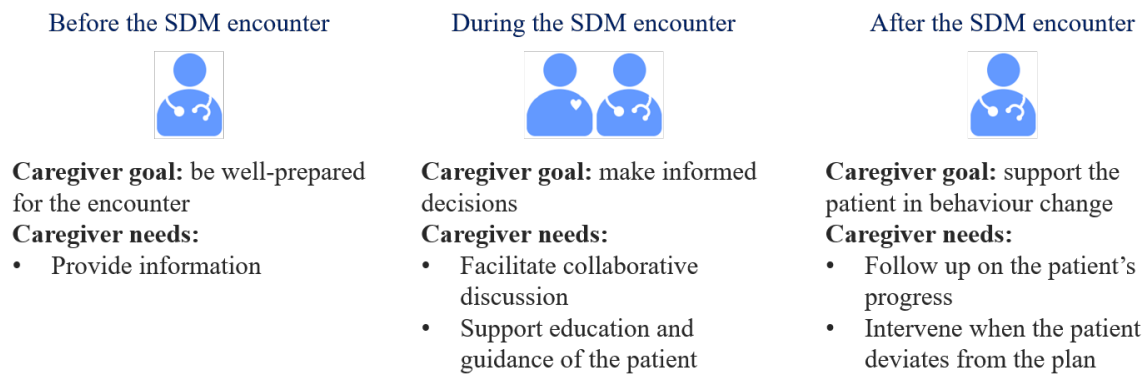


Figure 2: The caregiver's goals and needs preceding to, during, and after the SDM encounter.

ments in time, the support of the caregiver can help the patient getting back on track in case of difficulties.

As can be seen in Figure 1 and Figure 2, the goals and needs of the different stakeholders in the SDM process are not complementary, but in essence are the same goals from different (patient and caregiver) perspectives. When looking at the goals and needs of both stakeholders, we can conclude that these can be satisfied by a selection of the tools proposed in the categorization of Bonneux et al. (Bonneux et al., 2019). In the next section, we introduce a possible timeline for a single SDM encounter and present accompanying tools to satisfy the needs of the different stakeholders (patients and caregivers) in the context of secondary prevention of cardiovascular diseases.

3 TIMELINE FOR A SHARED DECISION MAKING ENCOUNTER

In this paper, we present the CoroPrevention-SDM approach, a technology-supported shared decision making approach for a comprehensive secondary prevention program for cardiac patients. As recommended by guidelines and EAPC position statements (Ambrosetti et al., 2021; Graham et al., 2017; Visseren et al., 2021), the CoroPrevention secondary prevention program implements a holistic approach that targets the risk factors for cardiovascular diseases and incorporates shared decision making. To satisfy all requirements that were stated above (i.e. offering a holistic approach for secondary prevention, supporting shared decision making, and satisfying all patient and caregiver needs identified in Section 2), we designed and developed the CoroPrevention Tool Suite. The CoroPrevention Tool Suite takes a holistic approach for secondary prevention by offering the fol-

lowing 7 modules, when it reaches the full target implementation: parameter monitoring, education, medication, physical activity, healthy nutrition, smoking cessation, and stress management (Figure 3). The modules in the Tool Suite are gradually elaborated further during the project. Most of these modules can directly be linked to the behavioural goals, i.e. medication adherence, start moving, healthy nutrition, smoke-free living, and stress relief. The two remaining modules, education and parameter monitoring, are essential to support the shared decision making process and remote follow-up by the caregiver.

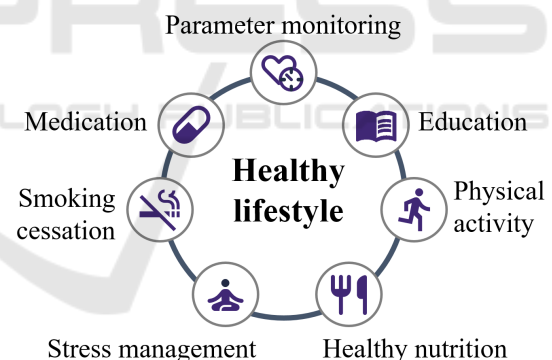


Figure 3: The seven modules of the CoroPrevention Tool Suite to implement a comprehensive secondary prevention program for cardiac patients.

The CoroPrevention Tool Suite is composed of three digital tools that support patients and caregivers in shared decision making for the secondary prevention program (Figure 4). The first tool is an extended ePRO application. In the context of the CoroPrevention Tool Suite, Electronic Patient-reported Outcomes (ePRO) are questionnaires for patients to indicate how they are feeling and what they prefer. Patients use the extended ePRO application on a tablet in the waiting room (prior to the SDM encounter) to inform themselves about the SDM process, report on their current status, and state their preferences. A

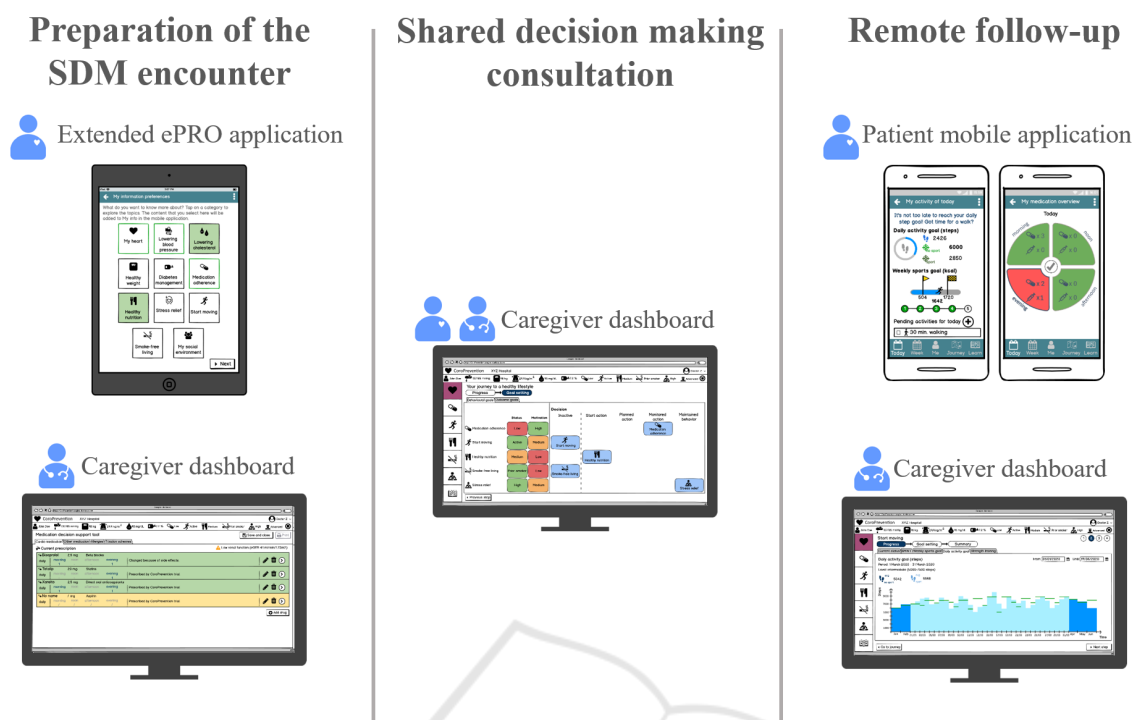


Figure 4: The timeline and accompanying tools to be used during a single encounter to support shared decision making for a comprehensive secondary prevention program.

caregiver dashboard with integrated clinical decision support systems and shared decision making support is the second tool of the CoroPrevention Tool Suite. This dashboard is used by caregivers to prepare for the encounter and to follow up on their patients between encounters. Furthermore, the caregiver dashboard can be used during a consultation on a shared display to encourage collaboration and spark discussion with the patient. The third tool is a smartphone application that patients use at home to follow up on their behaviour change process and receive support for decision-making in daily life. Figure 4 provides an overview of the usage of the different tools of the CoroPrevention Tool Suite for a single SDM encounter. The tools are categorized according to the three moments in time that were identified before: preceding to the SDM encounter, during the SDM encounter, and after the SDM encounter.

4 SHARED DECISION MAKING IN THE COROPREVENTION TOOL SUITE

In this section, we describe the CoroPrevention Tool Suite according to the timeline for a single encounter, i.e. preceding to the SDM encounter, during the SDM

encounter, and after the SDM encounter.

4.1 Preparation of the SDM Encounter

Given the short time available for live encounters (with an average of just about 10 minutes per patient (Elmore et al., 2016)), it is important that both patients and caregivers are well prepared for the encounter. To preserve more time during the encounter for shared decision making, patients can already provide a status update about their risk factors and related behavioural goals in the extended ePRO application preceding to the encounter. In shared decision making, it is crucial that the patient’s preferences are taken into account. These preferences can range from very high-level e.g. which goals would the patient like to work on, to very specific e.g. which sports activities does the patient like to perform. Patients might be unsure to state their preferences in front of their caregivers, because they are overwhelmed and did not expect that their caregivers would ask them about their preferences. Therefore, the patient’s preferences are collected before the SDM encounter in the extended ePRO application. These preferences are depicted on the shared display during the SDM encounter, which can encourage patients to talk about their preferences. For patients that might then still be reluctant to talk about them, the caregiver can take into account the

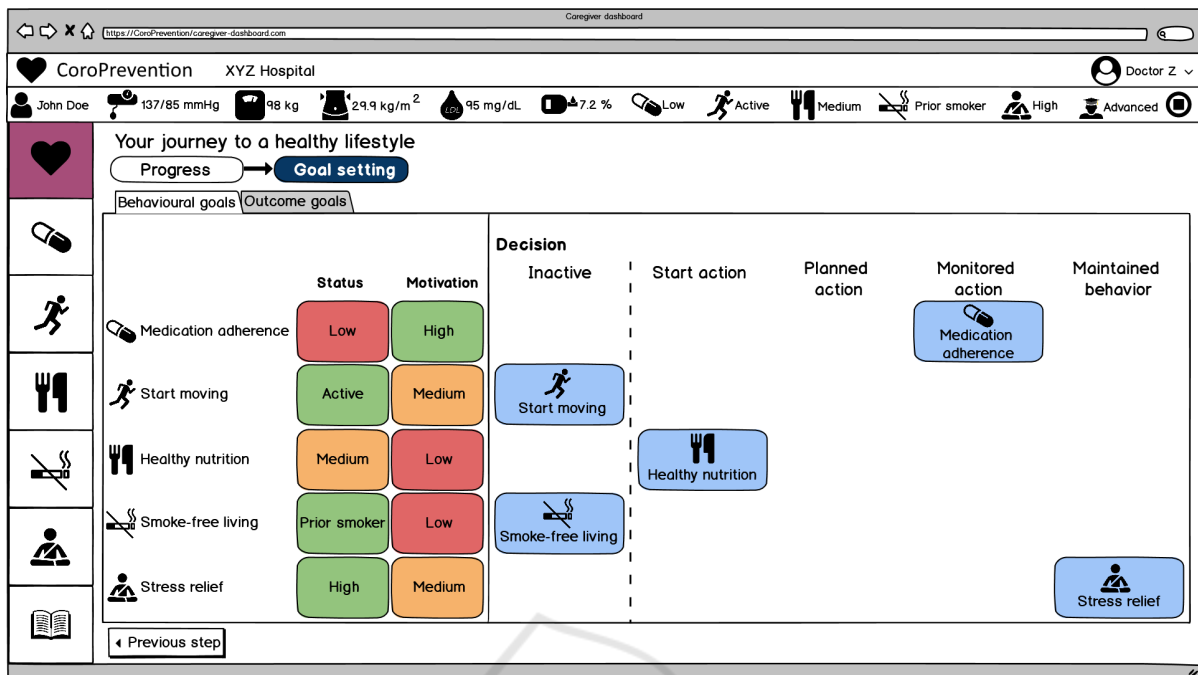


Figure 5: Goal setting of behavioural goals in the caregiver dashboard. The patient and caregiver discuss the patient's status and motivation for the behavioural goals and decide upon the patient's behavioural goals for the upcoming period.

preferences that were collected by the system. Collecting this information before the SDM encounter does not only lead to more time for decision-making during the encounter, but also provides patients a clear moment to reflect on their status, behaviour, and preferences. Furthermore, a video offered in the extended ePRO application before the first SDM encounter already provides the patient some information about shared decision making in general and familiarizes him/her with the process that will follow.

Next to patients, caregivers also need to be well-prepared for a SDM encounter. If desired, caregivers can prepare themselves for the encounter by checking the patient's performance in the last months and pending goals in the caregiver dashboard. Furthermore, clinical decision support systems (CDSS) can support caregivers in prescribing guideline-based care to their patients. In the CoroPrevention caregiver dashboard, we incorporated the EXPERT tool (Hansen et al., 2017a; Hansen et al., 2017b) for guideline-based exercise prescription and a decision support system for medication prescription. A detailed description of these systems is beyond the scope of this SDM article. Using DSS systems during encounters with patients can be cumbersome and might affect the patient's perception of the caregiver's credibility and authority. Also, using a clinical decision support system before the SDM encounter leaves more time during the SDM encounter to discuss the decisions that were

made with input of the CDSS, set goals, and decide upon the actions that the patient should take to achieve these goals.

4.2 Shared Decision Making Consultation

During the SDM encounter, the dashboard acts as a SDM tool that supports the shared decision making conversation between the caregiver and the patient. They start by discussing the patient's evolution in the past period and his/her current status for the behavioural goals and related outcome goals. For the outcome goals (e.g. lowering blood pressure, lowering cholesterol, and healthy weight), shared decision making is not possible in our approach, as these goals are determined based on clinical guidelines and the caregiver's expertise. Moreover, cholesterol and hypertension are more influenced by medication than by lifestyle changes. Therefore, the caregiver will strongly emphasize the importance of medication adherence to reduce the patient's CVD risk. Nevertheless, behaviour changes such as reducing salt intake, exercising more, and eating healthier can be other ways to work on these outcome goals. Therefore, it is still important to discuss the patient's outcome goals during the encounters. Based on the patient's outcome goals and status, the behavioural goals (e.g. increasing physical activity, eating healthier, and quit-

ting smoking) that the patient should work on from a clinical point of view can be determined and discussed (Figure 5). The patient's motivation (that was collected in the extended ePRO application) to work on these behavioural goals is depicted to spark discussion and encourage the patient to state his/her preferences. During the discussion, the patient and caregiver agree upon a feasible behavioural goal for the patient (i.e. decision-making level 1). After deciding upon the behavioural goal, they discuss and record the plans to achieve this goal (i.e. decision-making level 2 and possibly even decision-making level 3). If the patient and caregiver agree to set multiple behavioural goals, the process restarts to set the next behavioural goal. During this process, the caregiver's role is not only to support the patient in decision-making, but also to motivate the patient to work on the agreed behavioural goals. At the end of the SDM encounter, a feasible set of behavioural goals has been agreed upon and action plans have been recorded to support the patient in achieving these goals. This information is used to configure the mobile application that belongs to the CoroPrevention Tool Suite on the patient's smartphone, that will guide the patient until the next SDM encounter.

4.3 Remote Follow-up

Between SDM encounters, at home, the mobile application supports the patient in working on the behavioural goals and making smaller decisions in daily life (i.e. decision-making level 3). In the mobile application, patients receive support to make decisions on a daily basis (e.g. which sports activities will I perform today) and can follow up on their medication intake. Furthermore, they can record their progress (e.g. tracking sports activities) and follow up on their journey towards a healthy lifestyle. Based on the patient's progress, the mobile application makes recommendations to increase/decrease the support for the behavioural goals. However, patients can also decide themselves to start or stop working on a behavioural goal (patient autonomy) and as such, become the manager of their own disease. When the patient activates a new behavioural goal, the mobile application supports the patient in setting feasible goals and constructing action plans. However, there will also be moments when the patient has difficulties. At those moments, the mobile application (and caregivers) will be there to help the patient getting back on track. The data that is collected in the patient mobile application is used as input in the next SDM discussion.

Caregivers can follow up on their patients between visits by receiving alerts about their patients' progress

and behaviour, which can be consulted in the caregiver dashboard. Given the busy schedules of caregivers and the large number of patients that they have to supervise, it should be avoided that caregivers receive too many alerts. Therefore, some alerts are handled automatically by the CoroPrevention Tool Suite, without requiring input of the caregiver (e.g. sending tailored educational material to the patient to encourage the patient to take action). However, in some cases (e.g. when the patient's medication adherence is very low), caregivers may want to intervene (e.g. call the patient to assess barriers). The CoroPrevention caregiver dashboard facilitates this decision to caregivers by offering all information and triggering alerts with regard to the status of a patient.

5 FORMATIVE EVALUATION OF THE COROPREVENTION-SDM APPROACH

To the best of our knowledge, the concept of setting behavioural goals collaboratively during SDM encounters has not yet been investigated in the past in the context of secondary prevention of cardiovascular diseases. We assessed patients' and caregivers' opinion on our proposed shared decision making approach for secondary prevention as part of a formative usability study of the different applications of the CoroPrevention Tool Suite. The formative usability study was approved by the Medical Ethical Committees of Hasselt University and Jessa Hospital Hasselt. 10 cardiac patients and 7 caregivers were asked about their willingness to use the tools of our proposed SDM approach to set behavioural goals. After participants were acquainted with the caregiver dashboard and/or mobile application by performing an individual task-based formative usability test regarding some of the modules of the CoroPrevention Tool Suite, they filled in a custom-made questionnaire consisting of several Likert-scale questions. Caregivers were asked if they were willing to use a caregiver dashboard during their consultations with patients to discuss patients' progress and set goals for a healthy lifestyle. Similarly, patients were asked if they would be willing to use a caregiver dashboard during a consultation with a caregiver to discuss their progress and set goals for a healthy lifestyle. Furthermore, patients were asked if they would be willing to use a mobile application to follow up at home on their journey towards a healthy lifestyle.

The results of our survey are depicted in Figure 6. All participants (both patients and caregivers) unani-

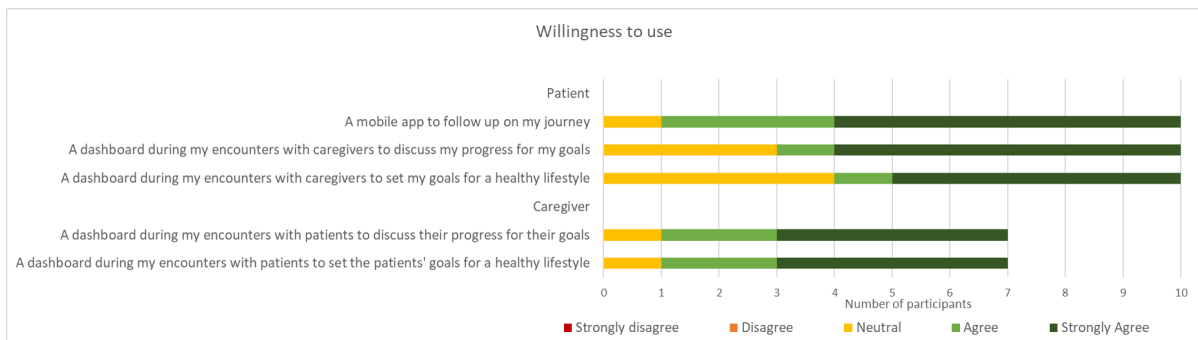


Figure 6: Patients' and caregivers' willingness to use the digital tools of the CoroPrevention Tool Suite.

mously agreed that they would be willing to use the proposed tools supporting the CoroPrevention-SDM approach. There were a few neutral responses. For the patients that participated in the study, these neutral responses might be due to the fact that the cardiac patients that participated in the usability study already completed cardiac rehabilitation quite a long time ago. Therefore, using these tools might be less relevant for them at this moment. As a minor limitation, we should note that there is a possibility for bias in favour of more motivated patients, due to the way in which we recruited our participants, i.e. people that already participated in cardiac rehabilitation and were willing to participate in a formative usability test.

6 CONTRIBUTIONS AND FUTURE DIRECTIONS

European guidelines and EAPC position statements (Ambrosetti et al., 2021; Graham et al., 2017; Visseren et al., 2021) recommend that secondary prevention programs offer a *holistic approach* and incorporate *shared decision making* as a means to engage patients. We are not aware of any existing system that offers this support at the time of writing this paper. Current systems include only some of the key components of secondary prevention and/or do not support shared decision making. This prompted us to design and develop a technology-supported shared decision making approach for a comprehensive secondary prevention program for cardiac patients.

6.1 Summary of Contributions

The contributions of this paper are the following:

- Bringing together patients' and caregivers' needs with the European guidelines and EAPC position statements for secondary prevention in a holistic, shared decision making approach for secondary

prevention of cardiovascular diseases;

- Incorporating the resulting needs in a Tool Suite that supports patients and caregivers in following a SDM approach for a comprehensive secondary prevention program;
- Deriving initial insights on collaborative goal-setting for behavioural goals based on a formative usability study of our proposed approach and accompanying tools with patients and caregivers.

In Figure 1 and Figure 2, we provided an overview of cardiac patients' and their caregivers' goals and associated needs for tools supporting SDM for a comprehensive secondary prevention program. During the design phase, this overview supported us in selecting features that support the target users and ensuring that the designed applications fit with end users' needs. We believe that the overview of goals and needs can be generalized to any eHealth intervention supporting shared decision making for a healthy lifestyle. Therefore, we hope that our overview can be useful for other researchers working in this field.

In this paper, we presented the CoroPrevention-SDM approach and accompanying Tool Suite consisting of three applications supporting a shared decision making approach for a comprehensive cardiac secondary prevention program. We illustrated how these tools align with the categorization of tools to support shared decision making of Bonneux et al. (Bonneux et al., 2019) and with our conceptual figures (Figure 1 and Figure 2). Furthermore, we gave a high-level overview of the core features of the different tools of the CoroPrevention Tool Suite. However, a detailed overview of the features and design of the different applications is out of scope for this paper.

Lastly, we evaluated our proposed CoroPrevention-SDM approach in a questionnaire that was part of a formative usability study. Our survey showed that both patients and caregivers are interested in using our proposed CoroPrevention Tool Suite to set behavioural goals during shared decision

making encounters. This gives a first indication of patients' and caregivers' willingness to use digital tools for SDM, but a more thorough investigation is needed to evaluate the impact of these tools on patient outcomes, such as health parameters, but also motivation and engagement in the decision-making process.

6.2 Future Directions

In our formative usability tests using wireframes, we collected preliminary insights on patients' and caregivers' willingness to follow our proposed CoroPrevention-SDM approach and evaluated the usability of the different applications of the CoroPrevention Tool Suite. Currently, our proposed CoroPrevention-SDM approach and supporting Tool Suite are in development, and gradually extended with additional modules. As a next step, we plan to investigate if the tools of the CoroPrevention Tool Suite support shared decision making. In a summative test with the application modules that will be used in the RCT, we will let patients and caregivers collaboratively set personalized goals during a SDM encounter.

Next, in the second half of 2022, a large-scale randomized controlled trial (RCT) will start to evaluate our proposed technology-supported shared decision making approach for a comprehensive secondary prevention program for cardiac patients (reference to <https://clinicaltrials.gov/> anonymized for review). In the RCT, 12000 coronary heart disease patients will be recruited across 6 European countries, of which 2000 high-risk patients will be enrolled in the nested RCT that evaluates the CoroPrevention-SDM approach and accompanying Tool Suite. Over a period of three years, patients and their supporting caregivers will use the CoroPrevention Tool Suite to set personalized goals for the patients and follow up on their progress. Human-Computer Interaction related outcomes will include the usability and user experience of the different tools, patients' motivation for behaviour change, and the influence of the Tool Suite on shared decision making.

7 CONCLUSIONS

In this paper, we identified varying needs and requirements for a holistic approach for a secondary prevention program for cardiovascular diseases. Based on these needs, we designed the CoroPrevention-SDM approach and accompanying Tool Suite. The CoroPrevention-SDM approach is a technology-supported shared decision making ap-

proach for a comprehensive secondary prevention program for cardiac patients. The CoroPrevention Tool Suite consists of three applications supporting our proposed approach: 1) an extended ePRO application to collect patient's status and preferences, 2) a caregiver dashboard with integrated clinical decision support systems and shared decision making support, and 3) a patient mobile application supporting behaviour change. A formative usability study of the applications indicated that both patients and caregivers are willing to use the designed applications and follow the CoroPrevention-SDM approach. A more thorough evaluation of our proposed approach and supporting applications is planned for early 2022.

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