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Understanding the healthcare providers' perspective for bringing the Assessment of Burden of Chronic Conditions tool to practice: a protocol for an implementation study

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Abstract

Introduction

The Assessment of Burden of Chronic Conditions (ABCC-) tool is developed and validated to support and facilitate a personalized approach to care for people with chronic conditions. The benefit of using the ABCC-tool greatly depends on how it is implemented. To enable a deeper understanding of when, how and by whom the ABCC-tool is used, this study protocol describes the design of an implementation study in which the context, experiences and implementation process of the ABCC-tool by primary care healthcare providers (HCPs) in the Netherlands will be investigated.

Methods and analysis

This protocol describes an implementation study alongside an effectiveness trial, in which the ABCC-tool is evaluated in general practices. The implementation strategy of the tool in the trial confines to providing written information and an instruction video explaining the technical use of the ABCC-tool. The implementation outcomes include a description of: 1) the barriers and facilitators of HCPs for implementation of the ABCC-tool, guided by the Consolidated Framework for Implementation Research (CFIR), 2) the implementation process guided by the Reach-Effect-Adoption-Implementation-Maintenance (RE-AIM) framework, 3) the intended use of the ABCC-tool by means of the Carroll's fidelity framework. All outcomes will be gathered through individual semi-structured interviews throughout 12 months of use. Interviews will be audio-recorded and transcribed. Transcripts will be analyzed using content analysis for identifying barriers and facilitators (based on CFIR) and thematic analyses of HCPs' experiences (based on the RE-AIM and the fidelity frameworks).

Ethics and dissemination

The presented study was approved by the Medical Ethics Committee of Zuyderland Hospital, Heerlen (METCZ20180131). Written informed consent prior is mandatory prior to participation

in the study. The results from the study in this protocol will be disseminated through publication in peer-reviewed scientific journals and conference presentations.

Key words: Assessment of Burden of Chronic Conditions (ABCC-) tool, burden of disease, patient-centered care, implementation, context, Consolidated Framework for Implementation Research (CFIR), process, RE-AIM, fidelity framework, general practice, primary care

Strengths and limitations of this study

- Implementation-effectiveness hybrid studies enable the combination of quantitative and qualitative outcomes, and therefore a better understanding of the complex reality of implementing novel interventions. These studies, however, are rarely conducted in primary care.
- Studying the determinants of implementation, implementation fidelity and implementation outcomes alongside an effectiveness trial bridges the gap between research and practice.
- The temporal design of this study enables to understand the development of identified barriers and facilitators to implementation over time.
- A limitation of this study is that the hybrid nature of this design does not allow for the deployment or alteration of implementation strategies during the effectiveness study.
- Patients' experiences are not studied in this presented study, but will be evaluated in a separate study.

Introduction

The shift from disease-centered care towards personalized care requires from healthcare providers (HCPs) to customize care to individual needs and collaborate on personalized treatment goals (1). This, however, demands from the HCP to understand each individual's experience of health or life in general. Patient Reported Outcome Measures (PROMs) can help HCPs to grasp a person's experience, and thus can make a difference when personalizing clinical practice. PROMs are questionnaires that measure a person's perspective on health-related outcomes such as quality of life (QoL) or wellbeing (2). These questionnaires are used in clinical practice at an increasing rate in order to improve and guide personalized care for people with various chronic conditions (3-5). The Assessment of Burden of Chronic Conditions (ABCC-) tool includes a PROM of which the outcomes are visualized into a balloon chart for easy comprehension. The tool is developed to guide care conversations towards the personal experienced burden of someone with Chronic Obstructive Pulmonary Disease (COPD), asthma, type 2 Diabetes Mellitus (T2DM), and/or chronic heart failure (CHF) (6, 7). The tool consists of a scale that validly and reliably measures a patient's experienced burden (i.e. the PROM), a visualization of the outcomes of that scale (figure 1), and domain-specific treatment advice based on the outcome of the scale (6-8). As such, the ABCC-tool enables HCP and patient to address the experienced burden and to formulate personalized goals for the domains of choice. The tool is now being evaluated for its effectiveness in improving patients' experienced quality of care (9). The transition of the ABCC-tool from the scientific development and evaluation phase towards routine clinical application is driven by implementation processes (4, 5, 10). Understanding these processes is key in understanding its effects as well as facilitating large-scale implementation of the ABCC-tool.

Implementation is a broad term describing all efforts that are made to bring an intervention, such as the ABCC-tool, to actual use in daily practice. These efforts are roughly divided in

efforts that either: 1) guide translation to clinical practice, 2) understand determinants of implementation, and/or 3) evaluate the actual implementation (11). With respect to the ABCC-tool, barriers and facilitators to actual use are determinants for implementation and can be identified in the context of the end user (12). Experiences with using the tool may either stimulate or hinder its use as it changes daily practice (13). It is also important to understand how the tool is actually being used, as this may not be identical to how it is intended (i.e. fidelity) (14). Knowing the determinants and the process of implementation enables clinicians to integrate the tool as part of routine care. In case of the ABCC-tool, the determinants of the implementation process, such as how HCPs' context and fidelity to the intervention influence the experiences of working with the ABCC-tool, are not yet known.

In order to understand the implementation of the ABCC-tool in general practices, the underlying determinants and process to implementation need to be understood. When these are understood, they can be used for improvements to the ABCC-tool to facilitate implementation at a larger scale. The aim of this paper is therefore to describe a study protocol for the assessment of 1) the barriers and facilitators for HCPs to implement the ABCC-tool, 2) the process of implementing the ABCC-tool, and 3) the fidelity of the ABCC-tool in general practices in the Netherlands.

Methods and analysis

The Standards for Reporting Implementation Studies (StaRI) were considered while composing this study protocol (see appendix 1) (15, 16). This implementation study will be conducted alongside an effectiveness trial (details of the effectiveness-part of the study are described elsewhere (9)). In short, a pragmatic clustered quasi-experimental study will be conducted in general practices in the Netherlands evaluating the ABCC-tool on patients' experience of

quality of care, quality of life, patient activation and healthcare costs. Patients from 18 intervention practices and 18 control practices will be followed for 18 months of using the ABCC-tool. HCPs will act as interventionists using the ABCC-tool in the effectiveness trial, while being the participants in the implementation study.

The ABCC-tool

The ABCC-tool is developed to guide the conversation between a HCP and a patient towards a personalized care plan, by integrating experienced burden in the conversation (6). The cycle of using the ABCC-tool contains several steps (figure 2). First, the patient completes a questionnaire regarding their experienced burden (i.e. with different scales for people with asthma, COPD, T2DM or CHF). Second, the outcomes of the questionnaire are digitally transformed into a balloon chart visualization (figure 1) (6). Third, both the HCP and patient discuss the presented balloons and pick one or more balloons of the patients choosing to elaborate on during that particular consultation. Upon clicking on one of the balloons, guideline-based treatment advice is presented as an in-screen pop-up. The fourth step in the cycle is to formulate a specific care goal and plan, fueled by the treatment advice and the possibilities and chances in the patient's context. Fifth, during the next consultation, the balloons that were visualized in the previous consultation are presented in grey while displaying the current balloons in color (see figure 1). Displaying the differences in this way allows for easy monitoring of the progress of experienced burden by the HCP and patient. The treatment advice that is used to build the personalized care plan also refers to using other eHealth applications, in between consultations with a GP or nurse, to achieve lifestyle goals. E-health applications can extend support to the home environment, while HCP consultations cover only a fraction of the time a patient spends to manage their own health (17). Therefore, the current

use of E-health applications will be included in the interview guide. The ABCC-tool will be used during each routine consultation as described above.

Population and recruitment

The target population in this study is HCPs in primary care, which will be recruited from the intervention arm of the effectiveness trial. All HCPs work in general practices in the Netherlands as general practitioner (GP), practice nurse, or nurse practitioner. For this study, HCPs are only eligible if they provided care for people with COPD, asthma, T2DM or CHF. These HCPs use either a specific General Practice Information System (i.e. MicroHIS) or an Integrated Care Information System (i.e. MediX) in which the ABCC-tool was technically integrated. Coding and analyses will be performed separately for two subgroups of participants based on whether they used either MicroHIS or MediX to use the ABCC-tool. The reason for this is that differences between these information systems exist in their users' context, access to the ABCC-tool (e.g. both HCP and patient can access the tool), and use of the ABCC-tool (e.g. patients complete the questionnaire digitally). Particularly, HCPs that use MediX are grouped in the same care group named ZIO (see box 1), while MicroHIS users are all individual HCPs. Studying these groups separately allows for the study of implementation in two distinct real-world contexts. A detailed description of these differences is provided in table 1. Because participating HCPs are interviewed during office hours, a total of three hours at an average practice nurse salary rate will be compensated to the practice in which they work.

Table 1: Description of distinctive subgroups.

	Individual HCPs	HCPs from ZIO care group
Context		
Region	Throughout the Netherlands	South of Limburg
Care group (see box 1)	Individual HCPs across various care groups	ZIO (Zorg In Ontwikkeling in Dutch; Care in development)
Coordination of the implementation	Individual coordination by the participating HCP	Centrally facilitated by care group in collaboration with practice managers
Access to ABCC-tool		
Provider of the ABCC-tool	Integrated third party (NHGDoc)	Digital patient environment (Sananet)
Costs	Free of charge during study period	Integrated in the collaboration between ZIO and Sananet; no additional costs on the HCP level
HCP access	Access button in MicroHIS directs to a different digital environment in which the ABCC-tool is shown/can be used	Access button reveals balloon chart directly in MediX
Using ABCC-tool		
Assessing burden	- Patient completes questionnaire on paper - HCP copies answers to the third party digital environment	- Patient completes the questionnaire digitally in patient environment (by phone or personal computer) - Completed questionnaires are automatically presented in MediX
Visualizing burden	- Balloons are presented in third party digital HCP environment - Patients cannot view balloons at home	- Balloons are presented in MediX - Patients can view balloons at home
Shared decision making	No differences between groups	
Formulating care goals	No differences between groups	
Monitoring	No differences between groups	

An overview of the differences between the two subgroups of HCPs in this study. Abbreviations: ABCC = Assessment of Burden of Chronic Conditions; ZIO = Zorg in Ontwikkeling (Dutch), which is the name of the participating care group

Context of care

In the Netherlands, provision of healthcare is layered based on its financial structure (18). Primary care in the Netherlands is provided by general practitioners at general practices, who act as a gatekeeper to secondary care (18). General practices in the Netherlands are either a single GP practice, multiple GP practice, or GP practice imbedded in a medical center (i.e.

single or multiple GP's collaborating with other primary care providers). General practitioners provide, as the name implies, care to people with any condition. Practice nurses and nurse practitioners in the Netherlands provide care for people with chronic somatic conditions (e.g. pulmonary disease, T2DM, cardiovascular disease, or a combination) or mental disease to a varying degree of independence (i.e. practice nurses are supervised by general practitioners whereas nurse practitioners are independent HCPs) (19). General practice-provided care in the Netherlands is strongly guided by the guidelines of the Dutch College of General Practitioners. As part of these guidelines, people with chronic conditions regularly visit their HCP when their condition is stable (i.e. once or twice a year for people with asthma or COPD, and four times a year for people with T2DM or CHF), or more often if necessary (20-23).

Box 1: Care groups in the Netherlands

A care group is a legal body in the Dutch healthcare system, in which multiple HCPs in primary care (i.e. most often a certain geographic region) are organized (24). Care groups in the Netherlands negotiate payment with health insurers and account for several organizational aspects of care. In this study, the care group ZIO (in Dutch: *Zorg In Ontwikkeling*) facilitates care provided by GPs, practice nurses and nurse practitioners in the south-eastern region of the Netherlands (i.e. the province of Limburg) centrally.

Study design

This implementation study consists of a follow-up period of 12 months, throughout which three separate evaluations take place to address the three objectives of this implementation study (figure 3). All evaluations will be performed as one-on-one qualitative semi-structured interviews with HCPs (25). Prior to using the ABCC-tool (T0) the context of the HCPs will be mapped using the Consolidated Framework for Implementation Research (CFIR) (26). The

description of the context will be used to identify barriers and facilitators to implementation. After three months (T1), a follow-up interview will be held to reflect on the first experiences with the ABCC-tool and the status of the identified barriers and facilitators from T0. If any other barriers or facilitators arise in the three months of use, they will be added to the list of barriers and facilitators that will be discussed during the next interview after 12 months. At T2, also a process evaluation of experiences, uptake into routine practice, and fidelity of the ABCC-tool will take place using the RE-AIM and fidelity frameworks. One researcher (DC) will perform all interviews to maintain stability in the interaction between the researcher and participant.

Sample size

Participants in this implementation study will be a subsample of the participating HCPs in the effectiveness trial. Empirically, qualitative data saturation is reached on average after 12-13 interviews (27). In a comparable qualitative evaluation of the ABCC-tool's predecessor (the ABC-tool specific for COPD), 9 out of 15 participants were sufficient to observe theoretical data saturation in a similarly homogeneous population. Therefore, a maximum of 15 participants are estimated to observe theoretical data saturation and to allow for transferability of the results (28, 29).

Implementation strategy

The ABCC-tool is implemented as an incorporated tool in the information systems that HCPs use. It is implemented in the same information systems as its predecessor, the Assessment of Burden of COPD tool (29-31). Prior experience of the HCP with this predecessor will be allowed for the HCP, but not for the patients who participate in the effectiveness trial. Regardless of prior knowledge, all HCPs will receive a document and an overview poster with

information on how to use the ABCC-tool, an explanation video presented by the researchers (accessible only with a specific weblink), and the ABCC-questionnaires for all conditions (i.e. COPD, asthma, T2DM, and CHF) as well as all possible combinations. HCPs will not be physically or digitally trained to use the ABCC-tool. However, they may have had training in the use of its predecessor. Whether participants have had training and/or experience will be asked during the first interview and will be included in the description of the context. Additional to the strategy described above, HCPs that use the Integrated Care Information System have more support during the trial. This support is primarily provided by staff from the care group and staff from the patient platform, and concerned recruitment of patients for the effectiveness trial and technical support. Researchers join in monthly meetings with the care group and patient platform staff to evaluate and assist in the implementation process. This additional support by the care group and patient platform justifies having two subgroups of participants in the analyses (individual HCPs versus HCPs from ZIO care group). To minimize the impact of the implementation study on the outcomes of the effectiveness study, all identified improvements will be implemented after the trial period. Only problems that would lead to the HCP not being able to use the ABCC-tool (i.e. technical errors) will be tackled during the study period.

Implementation outcomes

The implementation outcomes of this study are: 1) the barriers and facilitators for HCPs to implement the ABCC-tool, 2) the process of implementing the ABCC-tool, and 3) the fidelity of the ABCC-tool in general practices in the Netherlands. At the beginning of the study, the barriers and facilitators to implementing the ABCC-tool will be identified from the context of the participating HCPs using the CFIR (26). CFIR is a determinant framework to assess the presence of barriers or facilitators of study participants within their organization, and is often

used for studying the implementation of a PROM (or in this case a tool containing a PROM) (4, 11). CFIR defines five domains (i.e. intervention characteristics, inner setting, outer setting, individual characteristics, and process) containing 39 constructs that are known to influence implementation (26). The CFIR constructs are used to compose an interview guide that targets all constructs that are expected to be of influence on the implementation of the ABCC-tool in general practices in the Netherlands. A selection of CFIR constructs is made in order to minimize the time burden of the interview on HCPs to a maximum of 60 minutes while still focusing on the constructs that seem most relevant a priori. An overview of CFIR constructs and the choices whether or not to include them in the interview guide are presented in appendix 2. Identified barriers and facilitators will be followed up on during the two sequential interviews to evaluate how these barriers and facilitators are managed during the study period. HCPs will also be asked for any additional barriers and facilitators that are experienced after the first interview.

The Reach-Effectiveness-Adoption-Implementation-Maintenance (RE-AIM) framework will be used to evaluate the implementation process and will be assessed qualitatively (32-34). Reach will only be limitedly assessed because HCPs are instructed to recruit 10 eligible patients to participate in the study, and as such Reach is predetermined. The Effectiveness of the ABCC-tool will be evaluated as whether HCPs notice any influence of the ABCC-tool on patients, specifically in terms of quality of care, quality of life, or the level of active involvement in the care process. Objective effectiveness will not be evaluated in this implementation study. Adoption will be evaluated as the extent to which HCPs integrated the ABCC-tool into their routine practice. This includes whether the tool is being used by the GP, nurse practitioner and practice nurse. The Implementation domain of the RE-AIM framework constitutes fidelity, and will be evaluated in more depth using a fidelity framework (described below). Maintenance will

be evaluated as how HCPs are expecting to continue working with the ABCC-tool, how they see the future of the ABCC-tool in their practice, and whether steps are taken to actually maintain the use of the ABCC-tool.

Implementation fidelity refers to the adherence to the intervention as it is intended and will be evaluated using the framework for implementation fidelity by Carroll et. al. (14, 35). In this framework, fidelity is characterized as adherence to the intervention at four levels: content, coverage, frequency and duration. In order to adequately evaluate adherence to content, the ABCC-tool is described for all steps in the cycle of its use (figure 2). Evaluation of adherence to the ABCC-tool content will focus on how HCPs have used each separate step in this cycle, and whether this is performed as intended. The coverage of using the ABCC-tool will be evaluated as whether the tool was used in all participating patients. The frequency of use will be evaluated by whether the ABCC-tool is used in each regular visit of the patient, for at least 12 months. The in-consult duration of using the ABCC-tool is intended to be within the regular time for a consultation by a nurse practitioner, which is 20-30 minutes in the Netherlands. The time spent on the ABCC-tool will be evaluated qualitatively in order to assess whether this fell within this time frame and/or whether this was acceptable to the HCP. In the case that the use of the ABCC-tool is not as intended, reasons for this deviation will be explored. An interview topic guide of the process evaluation is presented in appendix 3.

Data analyses

All interviews will be audio-recorded, transcribed verbatim at literatim and anonymized. All interviews will be independently coded by two researchers. The T0 interview will be primarily processed using deductive coding according to the constructs of the CFIR. After this step, inductive coding will be applied to identify relevant factors that were not described in the CFIR

(i.e. these codes will be added to our framework for understanding HCPs in this particular context). The T1 interview will be completely processed using inductive coding. The T2 interview will be processed using deductive coding according to the domains that are formulated by the RE-AIM and fidelity frameworks. The data will be analyzed by one researcher and discussed with another researcher, upon disagreement a third researcher will decide. All data will be analyzed from a constructivist/interpretivist research paradigm, where understanding the subjective experience of HCPs is the main focus. As the T0 interview will be used to describe participants' context using the CFIR, a content analysis will be performed on the T0 interview to identify relevant contextual factors at play. From these contextual factors barriers and facilitators will be identified. As no theoretical framework is used for the T1 interview, a thematic analysis of the T1 interview will identify the themes that represent the lived experience of HCPs after three months of practice by means of phenomenology (36). As the T2 interview mainly includes personal experiences, a thematic analysis of the T2 interview will be performed to identify relevant themes within the boundaries of both frameworks (i.e. the interviews at T2 contain questions on the two frameworks, an overview of which is presented in appendix 3). By means of phenomenology, the experiences of using and implementing the ABCC-tool will be evaluated.

Patient and public involvement statement

Patients and patient advocacy groups, as well as healthcare providers (HCPs), were involved as an expert group from the development of the Assessment of Burden of Chronic Conditions (ABCC-)tool, the main intervention in this study protocol. HCPs or patients were not directly involved in the design or conduct of this protocol.

Discussion

The ABCC-tool is developed by, with, and for HCPs and people with chronic conditions (i.e. COPD, asthma, T2DM, and CHF). Understanding their perspective and experiences enables us to fully adapt the tool to meet their requirements and needs in clinical practice. The other way around, understanding how the ABCC-tool is used and implemented in a specific context, enables us to facilitate implementation in other settings. Understanding the extent to which HCPs have implemented the ABCC-tool in their routine practice, and which barriers and facilitators hinder or stimulate this, helps to identify how HCPs can optimally be supported in the implementation process. Lastly, knowing how the ABCC-tool is used and the reasons for deviations from the intended use, helps us to understand whether the ABCC-tool requires adjustments to local settings or whether specific training is necessary.

This study protocol describes an implementation study alongside an effectiveness trial. The major strength of the study lays in the hybrid nature of measuring effects in patients (i.e. recipients of the intervention) as well as studying the application and context of HCPs (i.e. providers of the intervention) (37). Another strength of this study design is the follow-up on contextual factors to the implementation of the ABCC-tool. This temporal design enables us to understand the development of barriers and facilitators over an extended period of use of the ABCC-tool. Possibly, some barriers may be solved by the passing of time (i.e. through experience or changing conditions) and new ones may arise. Alternatively, facilitators may also appear only as a temporary factor (i.e. only facilitating at the start). The use of the well-studied frameworks of CFIR, RE-AIM and the Fidelity framework from Carroll et al. strengthens the observations made during this study. The use of the CFIR additionally enables the selection of potential implementation strategies to resolve the identified barriers and facilitators through the Expert Recommendation for Implementing Change (ERIC-) tool (38, 39). These strategies are mapped on CFIR constructs to facilitate choosing ideal implementation strategies, though a

best-fit strategy should always match the local context. Lastly, studying the implementation in two contextually different groups enables us to empirically describe the similarities and differences between the two groups. The fact that HCPs from one group have a different organization of care and access to the intervention makes uniform conclusions rather difficult. However, implementation is always subject to local context and supports a case-by-case approach. The results from this implementation study enable us to describe not one, but two contextual cases for implementation and study the differences and similarities between those contexts.

A limitation of this study is that a selection of CFIR constructs is made. Possibly, relevant contextual factors will be missed because of this. However, evaluating the full scope of CFIR would be too time demanding. The selection was made with careful consideration of the trial design and the national context of primary care (see appendix 2) in several discussion rounds by three researchers (DC, MV, LD). Furthermore, due to the hybrid nature of this research, implementation strategies cannot be deployed until after the study period. In order to evaluate patient outcomes in the effectiveness trial, changes to the intervention or its implementation were not allowed during the trial. While this approach delays supporting the implementation process, it does allow barriers and facilitators to be followed and to develop implementation strategies to those determinants that are actually in need of support. Additionally, this study does not weigh in the experiences and context of participating patients in the effectiveness trial. In order to minimize the influence of this implementation study on the effect that is measured in patients, an evaluation of patient experiences is planned to take place after finalizing the data collection in the effectiveness trial. This will enable us to study the experiences of patients after an extended period of use while maintaining the integrity of current effectiveness measurements. The effectiveness trial also imposed limitations on the eligible population and the use of the full scope of the RE-AIM framework. With only a limited number of HCPs to

include in this implementation study, evaluating reach and organizational adoption will only be possible to some extent.

Accounting for the above mentioned strengths and limitations, this study will enable to explore the implementation of the ABCC-tool in a real world primary care setting. Studying the context of HCPs strengthens our understanding of their starting perspective for implementing a novel intervention such as this care-supporting tool. It also enables identification of (potential) barriers and facilitators as well as to follow their development over time. Understanding the local implementation process and difficulties facilitates the adaptation of the intervention and the design of appropriate implementation strategies for broad implementation. As such this study protocol is a first step towards the ABCC-tool's routine use in clinical practice in Dutch primary care.

Ethics and dissemination

Ethics approval and consent

The presented study was approved by the Medical Ethics Committee of Zuyderland Hospital, Heerlen (METCZ20180131). Written informed consent prior is mandatory prior to participation in the study. Transcripts from the qualitative interviews will be deidentified for the privacy of the participants.

Dissemination

The results from the study in this protocol will be disseminated through publication in peer-reviewed scientific journals and conference presentations. The participants of this study will be able to continue using the ABCC-tool after the study ends while the results from this study will

be used to facilitate implementation in other practices through the development of tailored implementation strategies.

Declarations

Competing interests

The authors declare that they have no competing interests.

Author's contributions

DC, MV and LD designed the study in close collaboration with EB, LK, AG and OS. DC wrote the first version of the manuscript of this study protocol under supervision of MV and LD. All authors have read and approved the final version of the manuscript.

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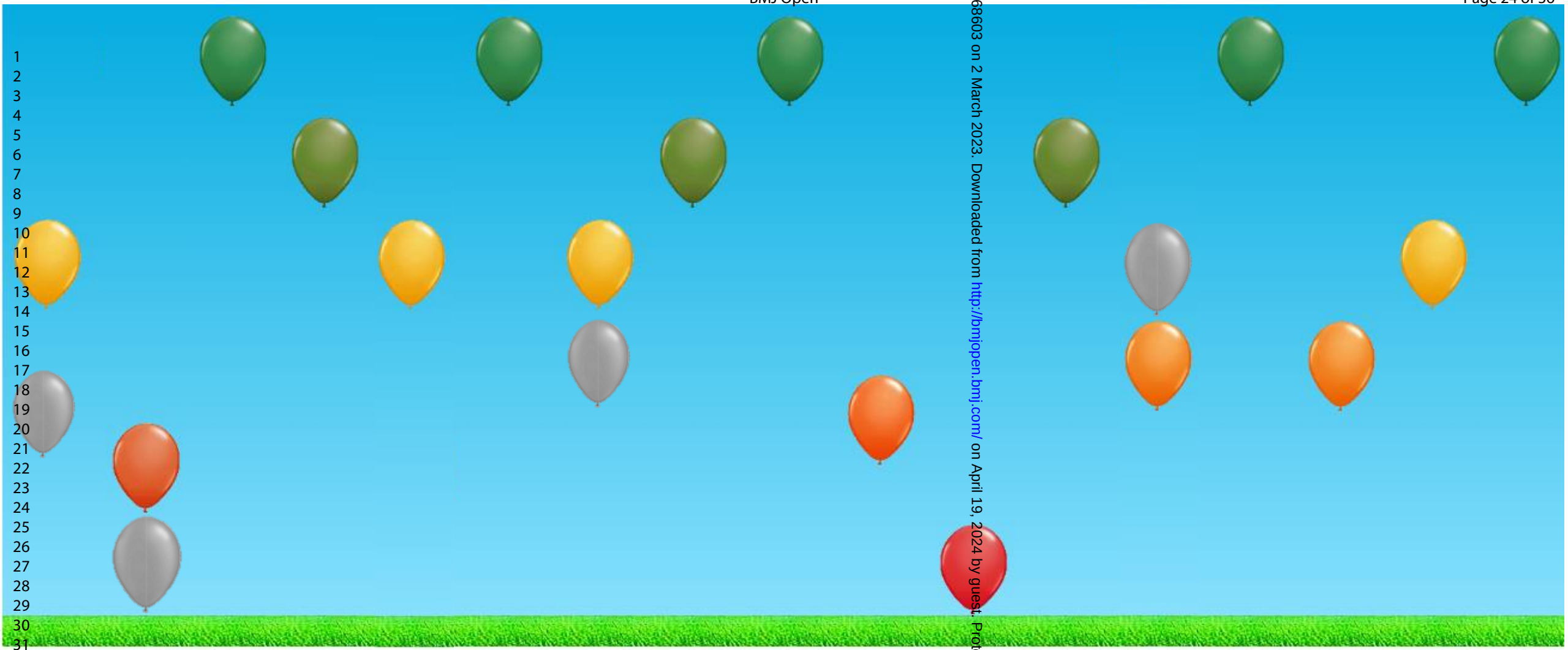
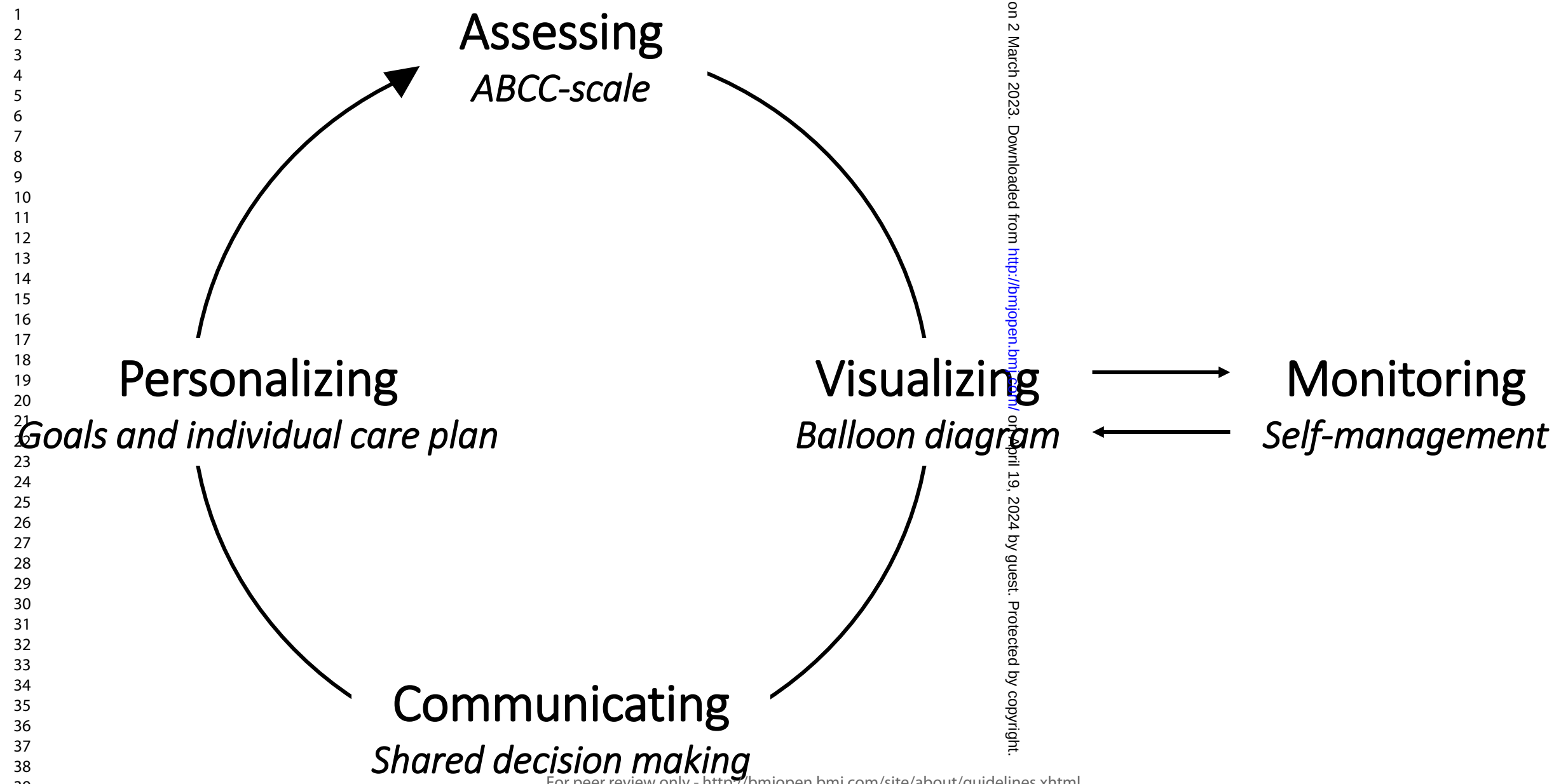
Figure 1: ABCC-tool visualization. An example of the visualization of the outcomes of the ABCC-tool, in this case for someone with COPD and T2DM. Each balloon represents a unique domain in the ABCC-tool. Green balloons indicate low burden, yellow balloons indicate moderate burden, and red balloons indicate high burden. Grey balloons indicate the score form the previous visit for comparison. A separate "questions" open field shows the additional topics or questions that the patient proposed in the questionnaire.

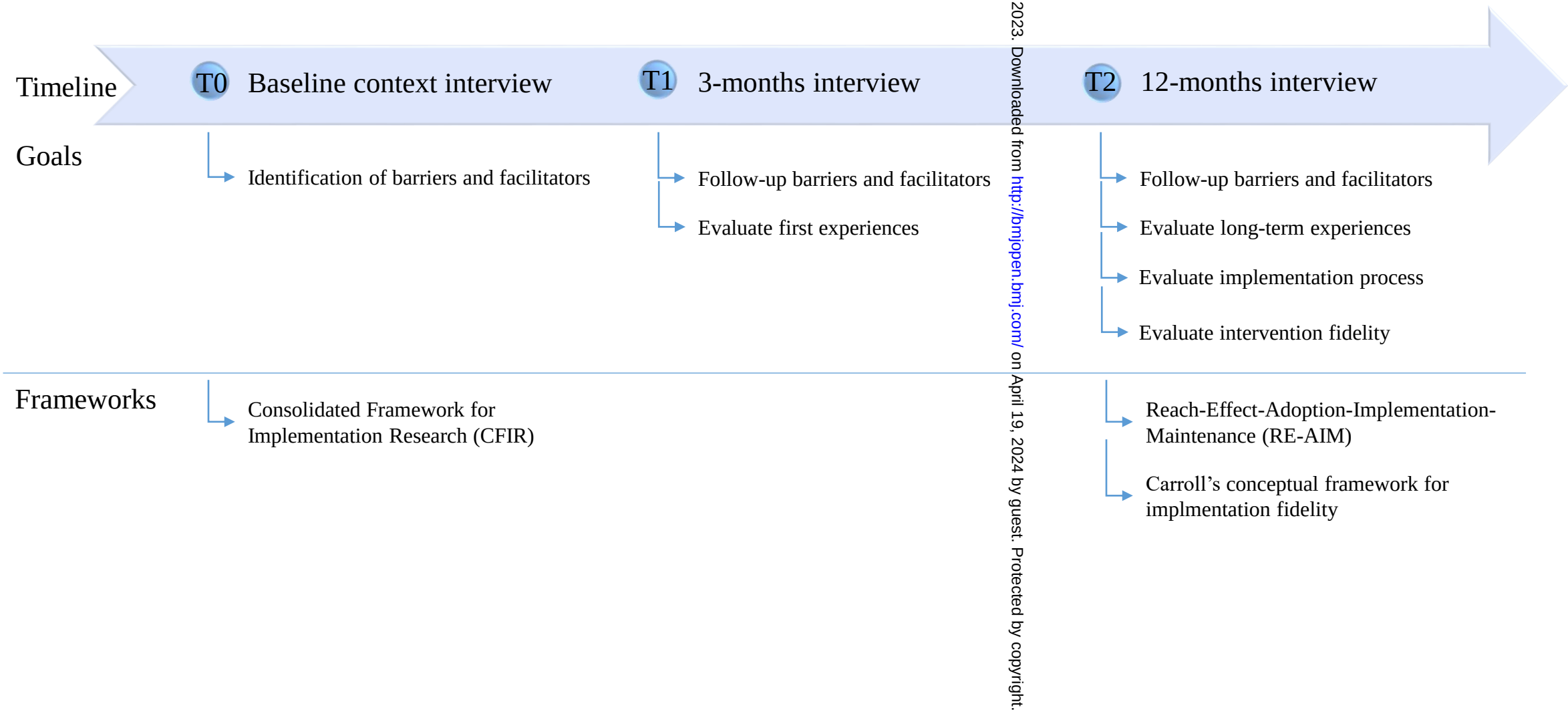
Figure 2: Process of using ABCC-tool. An overview of the cycle of using the ABCC-tool. The cycle starts at the assessing step, and then continues through the visualizing, communicating, and personalizing steps. After the initial evaluation, the visualizing step also facilitates the monitoring step because the balloons from the previous visit are presented in grey shades.

Figure 3: Overview of study design. An overview of planned interview moments, specified by the goals of the interview and used frameworks. T0 is the baseline interview prior to actual use, with T1 and T2 following after 3 and 12 months of use respectively.



Questions:





Standards for Reporting Implementation Studies: the StaRI checklist for completion

The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies (StaRI) statement. *BMJ* 2017;356:i6795

The detailed Explanation and Elaboration document, which provides the rationale and exemplar text for all these items is: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths C, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor S, for the StaRI group. Standards for Reporting Implementation Studies (StaRI). Explanation and Elaboration document. *BMJ Open* 2017 2017;7:e013318

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.	The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standardsrefers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	**1**	1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	**2**	1-2	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	**3**	3-5	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	**4**	10-11	The scientific background and rationale for the implementation strategy (including any underpinning	3-6	The scientific background and rationale for the intervention being implemented (including evidence

			theory/framework/model, how it is expected to achieve its effects and any pilot work).		about its effectiveness and how it is expected to achieve its effects).
Aims and objectives	**5**	5	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	**6**	5-6	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons.		
Context	**7**	7-8	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	**8**	7-8	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	7-8	The population targeted by the intervention and any eligibility criteria.
Description	**9**	10-11	A description of the implementation strategy	6	A description of the intervention
Sub-groups	**10**	7-8	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	**11**	11-13	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	N/A	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	**12**	11-13	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	**13**	N/A	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	**14**	10	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	**15**	13-14	Methods of analysis (with reasons for that choice)		
Sub-group analyses	**16**	13-14	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		

Results					
Characteristics	**17**	N/A	Proportion recruited and characteristics of the recipient population for the implementation strategy	N/A	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	**18**	N/A	Primary and other outcome(s) of the implementation strategy	N/A	Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	**19**	N/A	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	**20**	N/A	Resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	**21**	N/A	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/ adaptation	**22**	N/A	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	N/A	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	**23**	N/A	Contextual changes (if any) which may have affected outcomes		
Harms	**24**	N/A	All important harms or unintended effects in each group		
Discussion					
Structured discussion	**25**	14-17	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	**26**	17	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	17	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	**27**	18-19	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		

Additional file 1 Selection of CFIR constructs for the T0 interview topic guide

CFIR construct	Explanation *	Included	Reasons for not being included
Intervention characteristics			
Intervention source	Stakeholder's perception about development of de intervention (i.e. internal or external)	No	The ABCC-tool is implemented in a group of HCPs during an effectiveness trial. To maintain a comparable starting point, none of the HCPs could have participated in the development process.
Evidence strength and quality	Stakeholder's perception on the quality and validity of evidence supporting the intervention	No	The evidence supporting the ABCC-tool's desired outcomes is being gathered in the ongoing effectiveness trial. Thus, HCPs could not evaluate this at the starting point of the implementation study.
Relative Advantage	Stakeholders' perception of the advantage of implementing the intervention as opposed to another	Yes	-
Adaptability	Stakeholder's perception of the degree to which the intervention can be adapted to local needs	No	As the ABCC-tool is currently being evaluated, changes on the tool are not allowed. The goal of the study is to identify improvements, to be implemented after the study period.
Trialability	The ability to test the intervention on a small scale in the organization	No	As the implementation of the ABCC-tool takes place in a limited amount of patients (i.e. about 5 to 10 per practice), evaluating trialability within a trial seems trivial.
Complexity	The stakeholder's perceived difficulty with the intervention (e.g. duration, scope, disruptiveness, intricacy and number of required steps to use)	Yes	-
Design quality and packaging	Stakeholder's perceived excellence in how the intervention is presented	No	Evaluation of design and packaging was not included because part of the difficulty with design and packaging will come forth as an indication of complexity, while difficulty with the design will most probably come from patients, not HCPs, in this setting. Patients are interviewed separately in another study.
Cost	Costs of the intervention and costs associated with implementing the intervention	No	The ABCC-tool is free from direct costs, as the third party collaborators offer the tool freely. While indirect costs may also arise from changing the consultation, we expect that this may not be reflected in the HCPs experiences. A reflection of maintenance will be included in the T2 interview, which will include a reflection on the cost-benefit balance.
Outer setting			
Patient needs	The HCP's knowledge and priority on the patient's needs, as well as barriers and facilitators (e.g. patient-centeredness and skills of the patient)	Yes	-

Cosmopolitanism	The degree to which a network is present with other organizations	No	Though general practices are highly networked within other primary healthcare providers (i.e. such as physical therapy and psychology), the use of the ABCC-tool is possible only in the general practice.
Peer pressure	The competitive pressure to implement the intervention	No	Competition is less influential in primary care in the Netherlands as anyone is allowed free GP care. Competition may play a role in decisions at the buy-in of care between the provider and insurer, but the evidence of the ABCC-tool is not yet sufficient to influence those decisions.
External policies and incentives	A combination of all external strategies, policy and regulations that influence implementation of the intervention.	Yes	-
Inner setting			
Structural characteristics	The social characteristics of the organization (i.e. including age and size)	Yes	-
Networks and communications	The characteristics of the social network within the organization (i.e. nature and quality, and both formal and informal)	Yes	-
Culture	A combination of the norms, values and basic assumptions of the organization	Yes	-
Implementation climate	An umbrella-construct reflecting the absorptive capacity for change, receptivity, and reward for using the intervention. Sub-constructs of Implementation Climate (IC) are marked below	Yes	-
Tension for change (IC)	Stakeholder's perception of the current situation as tolerable or needing change	Yes	-
Compatibility (IC)	Stakeholder's perception of the degree of alignment of individual values with those that the intervention represents	Yes	-
Relative priority (IC)	The shared perception of importance of the intervention within the organization	Yes	-
Organizational incentives and rewards (IC)	The extrinsic incentives that result from using the intervention (e.g. goal awards, performance reviews, promotions, or stature)	No	Besides a compensation of working hours, no kind of rewards are coupled to using the ABCC-tool. Because of the strongly guideline-oriented primary care in the Netherlands, extrinsic incentives can only apply when the ABCC-tool is proven a best practice. And the evidence for that is still being gathered (i.e. effectiveness being some of that evidence).
Goals and feedback (IC)	The degree to which goals with respect to the intervention are communicated, acted upon, and feedback is given.	Yes	-

Learning climate (IC)	The stakeholders perception of whether the internal climate allows for: 1) leaders to express need for assistance and input, 2) team members to feel essential and valued, 3) individuals to feel psychologically safe, and 4) sufficient time and space for reflective thinking and evaluating	Yes	-
Readiness for implementation	An umbrella-construct reflecting the organization's commitment to implementing the intervention. Sub-constructs of Readiness for Implementation (RI) are marked below	Yes	-
Leadership engagement (RI)	Stakeholder's perception of the commitment, involvement and accountability of leaders and managers in the organization	Yes	-
Available resources (RI)	Stakeholder's perception of the resources needed for the implementation of the intervention (e.g. money, training, physical space, and time)	Yes	-
Access to knowledge and information (RI)	The stakeholder's perception of the access to digestible information about the intervention and how to incorporate it into the daily work tasks	No	HCPs received a brief document and poster on how the intervention works and how to use it in conversation. No training was provided, nor were there other experts or colleagues to discuss the intervention with because these HCPs are the first to use it. The results of this implementation study will eventually guide the development of a case-based training. However, at this phase we expected fewer experiences with the access to knowledge, and chose to leave it out for the sake of the interview duration.
Individual characteristics			
Knowledge and beliefs about the intervention	The stakeholder's individual attitudes and values with respect to the intervention, as well as familiarity with facts, truths and principles related to the intervention	Yes	
Self-efficacy	The stakeholder's individual belief in their own capabilities to execute the implementation of the intervention	Yes	
Individual stage of change	Characterization of the phase of change in which the individual is (i.e. towards a skilled, enthusiastic and sustained use)	No	Assessing the individual stage of change would invoke a more rigorous assessment, causing the total time span of the interview to fall well past 60 minutes. While acknowledging the importance of the stage of change, the selection of constructs did not include it.
Individual identification	The stakeholder's perception of their relation and commitment to their organization	Yes	

with the organization			
Other personal attributes	A broad construct containing all personal traits of the stakeholder (e.g. intellectual ability, motivation, values, competence, capacity and learning style)	Yes	
Process			
Planning	The degree to which a scheme or method for implementation is designed in advance, and the quality of these schemes	No	All process-constructs are left out of the interview for several reasons: 1) The HCPs are not likely capable to reflect on this as they are primarily involved in executing the intervention, but not in the other processes 2) General practices are mostly too small of an organization to have distinguished roles (i.e. opinion leaders, implementation leaders etc.). In most cases, this is one and the same person in a single practice. These constructs are more relevant for larger scale implementation projects (i.e. such as within an entire care group)
Engaging	An umbrella-construct reflecting the attraction and involvement of the appropriate individuals in the implementation and use of the intervention. Sub-constructs of Engagement (E) are marked below	No	
Opinion leaders (E)	The individuals in the organization that formally influence attitudes and beliefs in the organization (i.e. experts and peers)	No	
Formally appointed internal implementation leaders (E)	The individuals that are responsible for the implementation within the organization (e.g. coordinator, manager, or leader)	No	
Champions (E)	The individuals who dedicate themselves to implementing the intervention (e.g. through supporting, marketing, or overcoming resistance in the organization)	No	
External Change Agents (E)	The individuals outside of the organization who formally influence or facilitate implementation of the intervention	No	
Executing	Executing the intervention according to plan	No	
Reflecting and evaluating	Feedback about the progress and quality of the implementation, including regular debriefing about the progress	No	

Explanation and selection of CFIR constructs for the T0 interview guide. *All explanations are from the CFIR codebook, available at: https://cfirguide.org/guide/app/#/guide_select. The organization for all constructs is a general practice.

Additional file 2 Explanation of the T2 interview topic guide

Construct	Explanation
RE-AIM framework*	
Reach (not evaluated)	The absolute number/proportion and representativeness of individuals participating in the intervention as recipients (e.g. patients). This includes barriers and facilitators to participation, explanations regarding variations of participation across study sites, and reasons behind participation (or not). *This construct is not assessed in this present study because the number of participants is highly limited by the effectiveness study. . A proper evaluation of reach can therefore not be performed.*
Effectiveness	The impact of an intervention on important outcomes, such as potential negative effects, quality of life and economic outcomes. This includes the conditions and mechanisms that could lead to the effects, and explanations about the variation across study sites.
Adoption (not evaluated)	The absolute number/proportion and representativeness of individuals participating in the intervention as intervention agents (e.g. HCPs). Adoption can have multiple nested levels within an organization. This includes reasons that affect provider participation. *This construct is not assessed in this present study because the number of intervention agents is highly limited by those in the effectiveness study. A proper evaluation of adoption can therefore not be performed.*
Implementation (see fidelity)	The fidelity (adherence) to the key components of the intervention, including deviations and adaptations made and the underlying reasons. *This construct is evaluated in more detail using the fidelity framework described below.*
Maintenance	The extent to which the intervention becomes institutionalized or part of routine practice, and includes steps taken to ensure maintenance of the intervention in that particular general practice and barriers to sustained use.
Fidelity framework	
Content	The active ingredients of the intervention. The active ingredients are described below.
1) A scale measuring burden	The scale of the ABCC-tool is the first step in its five-step cycle. The scale should be completed by the patient (either digitally or with a paper-based questionnaire) and copied to the information system in case a paper-based questionnaire was used. All questions have to be answered for this step to be completed.
2) Visualization of burden	The visualization of the outcomes of the questionnaire, being the second step, is performed automatically by the information system upon clicking the "show balloon chart" button in-screen). The visualization should be clearly visible by both HCP and patient and used as guidance for the conversation topics.
3) Shared decision making	The HCPs should engage the patient to have an active role in the care conversation based on the principles of shared decision making in the third step. The shared decision making process should include: selecting balloons/domains as a topic of conversation together, exploring the burden within that domain, and opting for a personalized care plan.
4) Constructing a care plan	After the shared decision making process a personalized care plan is made in the. This care plan should be described as clearly as possible, for which we recommend the SMART-principles (40).
5) Monitoring the progress	After the patient is sent home, the fifth step of the cycle takes place: monitoring. The new assessment of burden is depicted in color, while the previous will be in grey. The HCP should compare both situations (i.e. height of the balloons) and use this information to monitor the patient's progress.
Coverage	These three constructs are more generally known and described as the dose of the intervention. The ABCC-tool should be used in all participating patients (i.e. coverage), during all check-up visits (i.e. frequency), and should take no longer than the regular available time period for a check-up (i.e. duration). The use of the ABCC-tool should be maintained throughout the study period (i.e. at least 12 months). The frequency of regular visits is dependent on the
Frequency	
Duration	

	condition (i.e. regular check-ups occur about once a year for people with COPD or asthma, and about four times a year for people with T2DM).
Constructs that did not originate from theoretical frameworks	
Experiences	The self-expressed lived experiences with working with the ABCC-tool. This construct is added to identify those aspects that have gained most attention from the HCP themselves, and which should at least be discussed.
Barriers and facilitators	The identified barriers and facilitators from the T0 and T1 interview are reflected upon again in this interview.
Training	An additional question is asked about whether training necessary for HCPs with no experience with the ABCC-tool, which aspects should be covered during a future training, to whom the training should be offered, and who should be the trainer.
Recommendation	To conclude the interview, the HCP is asked to reflect on whether they would recommend the ABCC-tool to a colleague, including the reasons behind their answer.

An overview of the frameworks used in the T2 interview, including additional questions that did not come from theoretical frameworks. * All explanation are directly from the RE-AIM website: https://www.re-aim.org/about/what-is-re-aim/ and the qualitative inquiries as suggested by the RE-AIM QUEST framework (34). ** The explanations are derived from those proposed by Carroll et al (14).

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Understanding the healthcare providers' perspective for bringing the Assessment of Burden of Chronic Conditions tool to practice: a protocol for an implementation study

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Understanding the healthcare providers' perspective for bringing the Assessment of Burden of Chronic Conditions tool to practice: a protocol for an implementation study

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Abstract

Introduction

The Assessment of Burden of Chronic Conditions (ABCC-) tool is developed and validated to support and facilitate a personalized approach to care for people with chronic conditions. The benefit of using the ABCC-tool greatly depends on how it is implemented. To enable a deeper understanding of when, how and by whom the ABCC-tool is used, this study protocol describes the design of an implementation study in which the context, experiences and implementation process of the ABCC-tool by primary care healthcare providers (HCPs) in the Netherlands will be investigated.

Methods and analysis

This protocol describes an implementation study alongside an effectiveness trial, in which the ABCC-tool is evaluated in general practices. The implementation strategy of the tool in the trial confines to providing written information and an instruction video explaining the technical use of the ABCC-tool. The outcomes include a description of: 1) the barriers and facilitators of HCPs for implementation of the ABCC-tool, guided by the Consolidated Framework for Implementation Research (CFIR), and 2) the implementation outcomes guided by the Reach-Effect-Adoption-Implementation-Maintenance (RE-AIM) framework Carroll's fidelity framework. All outcomes will be gathered through individual semi-structured interviews throughout 12 months of use. Interviews will be audio-recorded and transcribed. Transcripts will be analyzed using content analysis for identifying barriers and facilitators (based on CFIR) and thematic analyses of HCPs' experiences (based on the RE-AIM and the fidelity frameworks).

Ethics and dissemination

The presented study was approved by the Medical Ethics Committee of Zuyderland Hospital, Heerlen (METCZ20180131). Written informed consent is mandatory prior to participation in

the study. The results from the study in this protocol will be disseminated through publication in peer-reviewed scientific journals and conference presentations.

Key words: Assessment of Burden of Chronic Conditions (ABCC-) tool, burden of disease, patient-centered care, implementation, context, Consolidated Framework for Implementation Research (CFIR), process, RE-AIM, fidelity framework, general practice, primary care

Strengths and limitations of this study

- Implementation-effectiveness hybrid studies enable the combination of quantitative and qualitative outcomes, and therefore a better understanding of the complex reality of implementing novel interventions. These studies, however, are rarely conducted in primary care.
- Studying the determinants of implementation, implementation fidelity and implementation outcomes alongside an effectiveness trial bridges the gap between research and practice.
- The temporal design of this study enables to understand the development of identified barriers and facilitators to implementation over time.
- A limitation of this study is that the its design alongside an effectiveness trial does not allow for the deployment or alteration of implementation strategies during the effectiveness study.
- Patients' experiences are not studied in this presented study, but will be evaluated in a separate study.

Introduction

The shift from disease-centered care towards personalized care requires healthcare providers (HCPs) to customize care to individual needs and collaborate on personalized treatment goals (1). This, however, demands the HCP to understand each individual's experience of health or life in general. Patient Reported Outcome Measures (PROMs) can help HCPs to grasp a person's experience, and thus can make a difference when personalizing clinical practice. PROMs are questionnaires that measure a person's perspective on health-related outcomes such as quality of life (QoL) or wellbeing (2). These questionnaires are used in clinical practice at an increasing rate in order to improve and guide personalized care for people with various chronic conditions (3-5). The Assessment of Burden of Chronic Conditions (ABCC-) tool includes a PROM of which the outcomes are visualized into a balloon chart for easy comprehension. The tool is developed to guide care conversations towards the personal experienced burden of someone with Chronic Obstructive Pulmonary Disease (COPD), asthma, type 2 Diabetes Mellitus (T2DM), and/or chronic heart failure (CHF) (6, 7). The tool consists of a scale that validly and reliably measures a patient's experienced burden (i.e. the PROM), a visualization of the outcomes of that scale (figure 1), and domain-specific treatment advice based on the outcome of the scale (6-8). As such, the ABCC-tool enables HCP and patient to address the experienced burden and to formulate personalized goals for the domains of choice. The tool is now being evaluated for its effectiveness in improving patients' experienced quality of care (9). The transition of the ABCC-tool from the scientific development and evaluation phase towards routine clinical application is driven by implementation processes (4, 5, 10). Understanding these processes is key in understanding its effects as well as facilitating large-scale implementation of the ABCC-tool.

Implementation is a broad term describing all efforts that are made to bring an intervention, such as the ABCC-tool, to actual use in daily practice. These efforts are roughly divided in efforts that either: 1) guide translation to clinical practice, 2) understand determinants of implementation, and/or 3) evaluate the actual implementation (11). With respect to the ABCC-tool, barriers and facilitators to actual use are determinants of implementation and can be identified in the context of the end user (12). Experiences with using the tool may either stimulate or hinder its use as it changes daily practice (13). It is also important to understand how the tool is actually being used, as this may not be identical to how it is intended (i.e. fidelity) (14). Knowing the determinants and the process of implementation enables the development of tailored implementation strategies that support clinicians in integrating the tool as part of routine care. In case of the ABCC-tool, the determinants of the implementation process, such as how HCPs' context and fidelity to the intervention influence the experiences of working with the ABCC-tool, are not yet known.

In order to understand the implementation of the ABCC-tool in general practices, the underlying determinants and process to implementation need to be understood. When these are understood, they can be used for improvements to the ABCC-tool, as well as the development of tailored implementation strategies, to facilitate implementation at a larger scale. The aim of this paper is therefore to describe a study protocol for the assessment of 1) the barriers and facilitators for HCPs to implement the ABCC-tool, and 2) implementation outcomes concerning the ABCC-tool in general practices in the Netherlands.

Methods and analysis

The Standards for Reporting Implementation Studies (StaRI) were considered while composing this study protocol (see appendix 1) (15, 16). This implementation study will be conducted

alongside an effectiveness trial (details of the effectiveness-part of the study are described elsewhere (9)). In short, a pragmatic clustered quasi-experimental study will be conducted in general practices in the Netherlands evaluating the effect of the ABCC-tool on patients' perceived quality of care, quality of life, patient activation, capability well-being and costs. Patients from 18 intervention practices and 18 control practices will be followed for 18 months. HCPs will act as interventionists using the ABCC-tool in the effectiveness trial while being the participants in the implementation study.

The ABCC-tool

The ABCC-tool is developed to guide the conversation between a HCP and a patient towards a personalized care plan, by integrating experienced burden in the conversation (6). The cycle of using the ABCC-tool contains several steps (figure 2). First, the patient completes a questionnaire regarding their experienced burden (i.e. with different scales for people with asthma, COPD, T2DM or CHF). Second, the outcomes of the questionnaire are digitally transformed into a balloon chart visualization (figure 1) (6). Third, both the HCP and patient discuss the presented balloons and pick one or more balloons of the patients choosing to elaborate on during that particular consultation. Upon clicking on one of the balloons, guideline-based treatment advice is presented as an in-screen pop-up. The fourth step in the cycle is to formulate a specific care goal and plan, fueled by the treatment advice and the possibilities and chances in the patient's context. Fifth, during the next consultation, the balloons that were visualized in the previous consultation are presented in grey while displaying the current balloons in color (see figure 1). Displaying the differences in this way allows for easy monitoring of the progress of experienced burden by the HCP and patient. . Aside from the practical components of the ABCC-tool, several other core components are key to its application but are of adaptable nature. In order to facilitate quick application, HCPs are

instructed to have patients prepare the questionnaire at home or in the waiting room, prior to the actual consultation. HCPs are further instructed to facilitate an active patient participation in the choosing and discussing of relevant domains (balloons), applying the principles of shared-decision making (17). Another key component of the ABCC-tool is to formulate concrete and clear care goals and plans using the SMARTi-principles (18), and to monitor a patient's progress during the beginning of the next consultation. The ABCC-tool will be used during each routine consultation as described above.

Population and recruitment

The target population in this study comprises HCPs in primary care, which will be recruited from the intervention arm of the effectiveness trial. All HCPs work in general practices in the Netherlands as general practitioner (GP), practice nurse, or nurse practitioner. For this study, HCPs are only eligible if they provided care for people with COPD, asthma, T2DM or CHF. These HCPs use either a specific General Practice Information System (i.e. MicroHIS) or an Integrated Care Information System (i.e. MediX) in which the ABCC-tool was technically integrated. Coding and analyses will be performed separately for two subgroups of participants based on whether they used either MicroHIS or MediX to use the ABCC-tool. The reason for this is that differences between these information systems exist in their users' context, access to the ABCC-tool (e.g. both HCP and patient can access the tool), and use of the ABCC-tool (e.g. patients complete the questionnaire digitally). Particularly, HCPs that use MediX are grouped in the same care group named ZIO (see box 1), while MicroHIS users are HCPs from various care groups. Studying these groups separately allows for the study of implementation in two distinct real-world contexts. A detailed description of these differences is provided in table 1. Because participating HCPs are interviewed during office hours, a total of three hours at an average practice nurse salary rate will be compensated to the practice in which they work.

Table 1: Description of distinctive subgroups.

	MediX-users	MicroHIS-users
Context		
Region	Throughout the Netherlands	South of Limburg
Care group (see box 1)	Individual HCPs across various care groups	ZIO (Zorg In Ontwikkeling in Dutch; Care in development)
Coordination of the implementation	Individual coordination by the participating HCP	Centrally facilitated by care group in collaboration with practice managers
Access to ABCC-tool		
Provider of the ABCC-tool	Integrated third party (NHGDoc)	Digital patient environment (Sananet)
Costs	Free of charge during study period	Integrated in the collaboration between ZIO and Sananet; no additional costs on the HCP level
HCP access	Access button in MicroHIS directs to a different digital environment in which the ABCC-tool is shown/can be used	Access button reveals balloon chart directly in MediX
Using ABCC-tool		
Assessing burden	- Patient completes questionnaire on paper - HCP copies answers to the third party digital environment	- Patient completes the questionnaire digitally in patient environment (by phone or personal computer) - Completed questionnaires are automatically presented in MediX
Visualizing burden	- Balloons are presented in third party digital HCP environment - Patients cannot view balloons at home	- Balloons are presented in MediX - Patients can view balloons at home
Shared decision making	No differences between groups	
Formulating care goals	No differences between groups	
Monitoring	No differences between groups	

An overview of the differences between the two subgroups of HCPs in this study. Abbreviations: ABCC = Assessment of Burden of Chronic Conditions; ZIO = Zorg in Ontwikkeling (Dutch), which is the name of the participating care group

Context of care

In the Netherlands, provision of healthcare is layered based on its financial structure (19). Primary care in the Netherlands is provided by general practitioners at general practices, who act as a gatekeeper to secondary care (19). General practices in the Netherlands are either a single GP practice, multiple GP practice, or GP practice imbedded in a medical center (i.e.

single or multiple GP's collaborating with other primary care providers). General practitioners provide, as the name implies, care to people with any condition. Practice nurses and nurse practitioners in the Netherlands provide care for people with chronic somatic conditions (e.g. pulmonary disease, T2DM, cardiovascular disease, or a combination) or mental disease to a varying degree of independence (i.e. practice nurses are supervised by general practitioners whereas nurse practitioners are independent HCPs) (20). General practice-provided care in the Netherlands is strongly guided by the guidelines of the Dutch College of General Practitioners. As part of these guidelines, people with chronic conditions regularly visit their HCP when their condition is stable (i.e. once or twice a year for people with asthma or COPD, and four times a year for people with T2DM or CHF), or more often if necessary (21-24).

Box 1: Care groups in the Netherlands

A care group is a legal body in the Dutch healthcare system, in which multiple HCPs in primary care (i.e. most often a certain geographic region) are organized (25). Care groups in the Netherlands negotiate payment with health insurers and account for several organizational aspects of care. In this study, the care group ZIO (in Dutch: *Zorg In Ontwikkeling*) facilitates care provided by GPs, practice nurses and nurse practitioners in the south-eastern region of the Netherlands (i.e. the province of Limburg) centrally.

Study design

This implementation study consists of a follow-up period of 12 months, throughout which three separate evaluations take place to address the three objectives of this implementation study (figure 3). All evaluations will be performed as one-on-one qualitative semi-structured interviews with HCPs (26). Prior to using the ABCC-tool (T0) the context of the HCPs will be mapped using the Consolidated Framework for Implementation Research (CFIR) (27). The

description of the context will be used to identify barriers and facilitators to implementation. After three months (T1), a follow-up interview will be held to reflect on the first experiences with the ABCC-tool and the status of the identified barriers and facilitators from T0. If any other barriers or facilitators arise in the three months of use, they will be added to the list of barriers and facilitators that will be discussed during the next interview after 12 months. At T2, also a process evaluation of experiences, uptake into routine practice, and fidelity of the ABCC-tool will take place using the RE-AIM and fidelity frameworks. Participant will remain the same throughout the study period (i.e. three consecutive interviews per participant). One researcher (DC) will perform all interviews to maintain stability in the interaction between the researcher and participant.

Sample size

Participants in this implementation study will be a subsample of the participating HCPs in the effectiveness trial, and thus a convenience sample. Empirically, qualitative data saturation is reached on average after 12-13 interviews (28). In a comparable qualitative evaluation of the ABCC-tool's predecessor (the ABC-tool specific for COPD), 9 out of 15 participants were sufficient to observe theoretical data saturation in a similarly homogeneous population. Therefore, a maximum of 15 participants per group are estimated to observe theoretical data saturation and to allow for transferability of the results (29, 30).

Implementation strategy

Several non-directed implementation strategies are deployed to facilitate clinicians to use the tool. First, the ABCC-tool is implemented as an incorporated tool in the information systems that HCPs use, and not in a separate environment. A stand-alone program was previously identified a barrier to the implementation of the ABCC-tool's predecessor, the Assessment of

Burden of COPD tool (30-32) (tailoring strategies from the Expert Recommendations for Implementing Change (ERIC) (33, 34)). Prior experience of the HCP with this predecessor will be allowed for the HCP, but not for the patients who participate in the effectiveness trial. Second, regardless of prior knowledge, all HCPs will receive a document and an overview poster with information on how to use the ABCC-tool, and an explanation video presented by the researchers which is accessible only with a specific weblink (i.e. development and distribution of educational materials from ERIC (33, 34)). HCPs will not be physically or digitally trained to use the ABCC-tool. However, they may have had training in the use of its predecessor. Whether participants have had training and/or experience will be asked during the first interview and will be included in the description of the context. Additional to the strategy described above, HCPs that use the Integrated Care Information System have more support during the trial because they are all part of the same care group. Researchers join in monthly meetings with the care group and patient platform staff to evaluate and assist in the implementation process (i.e. build a coalition from ERIC (33, 34)). This support is primarily provided by staff from the care group and staff from the patient platform, and concerned help in the recruitment of patients for the effectiveness trial and technical support (i.e. provide local technical assistance from ERIC (33, 34)). This additional support by the care group and patient platform was not possible for HCPs outside of the participating care group and justifies having two subgroups of participants in the analyses (MicroHIS-users versus MediX-users). To minimize the impact of the implementation study on the outcomes of the effectiveness study, all identified improvements will be implemented after the trial period. Only problems that would lead to the HCP not being able to use the ABCC-tool (i.e. technical errors) will be tackled during the study period.

Study outcomes

The outcomes of this study are divided as: 1) determinants of implementation (the barriers and facilitators for HCPs to implement the ABCC-tool), 2) implementation outcomes.

Participant demographics will be collected regarding: practice size, type of practice (GP practice or medical center), experience using the intervention's predecessor, age, sex, education (higher education, vocational education as either nurse or doctor's assistant), function (general practitioner, nurse practitioner or practice nurse), target population (COPD, asthma, diabetes mellitus type 2, heart failure, or a combination), and an estimate of the target population's socio-economic status (as viewed by the HCP).

At the beginning of the study and as determinants of the implementation process, the barriers and facilitators to implementing the ABCC-tool will be identified from the context of the participating HCPs using the CFIR (27). CFIR is a determinant framework to assess the presence of barriers or facilitators of study participants within their organization, and is often used for studying the implementation of a PROM (or in this case a tool containing a PROM) (4, 11). CFIR defines five domains (i.e. intervention characteristics, inner setting, outer setting, individual characteristics, and process) containing 39 constructs that are known to influence implementation (27). The CFIR constructs are used to compose an interview guide that targets all constructs that are expected to be of influence on the implementation of the ABCC-tool in general practices in the Netherlands. A selection of CFIR constructs is made in order to minimize the time burden of the interview on HCPs to a maximum of 60 minutes while still focusing on the constructs that seem most relevant a priori. A selection of relevant CFIR constructs was made by three researchers (DC, MV, LD) over the course of multiple discussion rounds and based on consensus. Trial design implications and the context of Dutch primary care were taken into account when evaluating the informative value of each CFIR construct. An

overview of CFIR constructs and the choices whether or not to include them in the interview guide are presented in appendix 2. Identified barriers and facilitators will be followed up on during the two sequential interviews to evaluate how these barriers and facilitators are managed during the study period. HCPs will also be asked for any additional barriers and facilitators that are experienced after the first interview.

Implementation outcomes will be qualitatively evaluated using the Reach-Effectiveness-Adoption-Implementation-Maintenance (RE-AIM) framework (35-37). Reach will only be limitedly assessed because HCPs are instructed to recruit 10 eligible patients to participate in the study, and as such Reach is predetermined. The Effectiveness of the ABCC-tool will be evaluated as whether HCPs notice any influence of the ABCC-tool on patients, specifically in terms of quality of care, quality of life, or the level of active involvement in the care process. Objective effectiveness will not be evaluated as this is part of the effectiveness study. Adoption will be evaluated as the extent to which HCPs integrated the ABCC-tool into the consultations with the participating patients. This also includes whether the tool is being used by the GP, nurse practitioner and/or practice nurse. The Implementation domain of the RE-AIM framework constitutes fidelity, and will be evaluated in more depth using a fidelity framework (described below). Maintenance will be evaluated as how HCPs are expecting to continue working with the ABCC-tool, how they see the future of the ABCC-tool in their practice, and whether steps are taken to actually maintain the use of the ABCC-tool.

Implementation fidelity refers to the adherence to the intervention as it is intended and will be evaluated using the framework for implementation fidelity by Carroll et. al. (14, 38). In this framework, fidelity is characterized as adherence to the intervention at four levels: content, coverage, frequency and duration. In order to adequately evaluate adherence to content, the

ABCC-tool is described for all steps in the cycle of its use (figure 2). Evaluation of adherence to the ABCC-tool content will focus on how HCPs have used each separate step in this cycle, and whether this is performed as intended. The coverage of using the ABCC-tool will be evaluated as whether the tool was used in all participating patients. The frequency of use will be evaluated by whether the ABCC-tool is used in each regular visit of the patient, for at least 12 months. The in-consult duration of using the ABCC-tool is intended to be within the regular time for a consultation by a nurse practitioner, which is 20-30 minutes in the Netherlands. The time spent on the ABCC-tool will be evaluated qualitatively in order to assess whether this fell within this time frame and/or whether this was acceptable to the HCP. In the case that the use of the ABCC-tool is not as intended, reasons for this deviation will be explored. An interview topic guide of the process evaluation is presented in appendix 3.

Data analyses

All interviews will be audio-recorded, transcribed verbatim at literatim and anonymized. All interviews will be independently coded by two researchers. Analyses are described per interview moment, and for each outcome separately.

The T0 interview will be primarily processed using deductive coding according to the constructs of the CFIR. After this step, inductive coding will be applied to identify relevant factors that were not described in the CFIR (i.e. these codes will be added to our framework for understanding HCPs in this particular context). As the T0 interview will be used to describe participants' context using the CFIR, a content analysis will be performed on the data of the T0 interview to identify relevant contextual factors at play. From these contextual factors, barriers and facilitators will be identified.

The T1 interview will be completely processed using inductive coding. As no theoretical framework is used for the T1 interview, a thematic analysis of the T1 interview will identify the themes that represent the lived experience of HCPs after three months of practice by means of phenomenology (39).

The T2 interview will be processed using deductive coding according to the domains that are formulated by the RE-AIM and fidelity frameworks. The data will be analyzed by one researcher (DC) and discussed with another researcher (MV), upon disagreement a third researcher (LD) will decide. All data will be analyzed from a constructivist/interpretivist research paradigm, where understanding the subjective experience of HCPs is the main focus. As the T2 interview mainly includes personal experiences, a thematic analysis of the T2 interview will be performed to identify relevant themes within the boundaries of both frameworks (i.e. the interviews at T2 contain questions on the two frameworks, an overview of which is presented in appendix 3). By means of phenomenology, the experiences of using and implementing the ABCC-tool will be evaluated.

Patient and public involvement statement

Patients, patient advocacy groups, and as healthcare providers (HCPs) were involved as an expert group during the development of the Assessment of Burden of Chronic Conditions (ABCC-)tool, the main intervention in this study protocol. HCPs or patients were not directly involved in the design or conduct of this protocol.

Discussion

The ABCC-tool is developed by, with, and for HCPs and people with chronic conditions (i.e. COPD, asthma, T2DM, and CHF). Understanding their perspective and experiences enables us

to fully adapt the tool to meet their requirements and needs in clinical practice. The other way around, understanding how the ABCC-tool is used and implemented in a specific context, enables us to facilitate implementation in other settings. Understanding the extent to which HCPs have implemented the ABCC-tool into the consultation with patients, and which barriers and facilitators hinder or stimulate this, helps to identify how HCPs can optimally be supported in the implementation process. Lastly, knowing how the ABCC-tool is used and the reasons for deviations from the intended use, helps us to understand whether the ABCC-tool requires adjustments to local settings or whether specific training is necessary.

This study protocol describes an implementation study alongside an effectiveness trial. The major strength of the study lays in the hybrid nature of measuring effects in patients (i.e. recipients of the intervention) as well as studying the application and context of HCPs (i.e. providers of the intervention) (40). Another strength of this study design is the follow-up on contextual factors to the implementation of the ABCC-tool. This temporal design enables us to understand the development of barriers and facilitators over an extended period of use of the ABCC-tool. Possibly, some barriers may be solved by the passing of time (i.e. through experience or changing conditions) and new ones may arise. Alternatively, facilitators may also appear only as a temporary factor (i.e. only facilitating at the start). The use of the well-studied frameworks of CFIR, RE-AIM and the Fidelity framework from Carroll et al. strengthens the observations made during this study. The use of the CFIR additionally enables the selection of potential implementation strategies to resolve the identified barriers and facilitators through the Expert Recommendation for Implementing Change (ERIC-) tool (33, 34). These strategies are mapped on CFIR constructs to facilitate choosing ideal implementation strategies, though a best-fit strategy should always match the local context. Lastly, studying the implementation in two contextually different groups enables us to empirically describe the similarities and

differences between the two groups. The fact that HCPs from one group have a different organization of care and access to the intervention makes uniform conclusions rather difficult. However, implementation is always subject to local context and supports a case-by-case approach. The results from this implementation study enable us to describe the relevant contextual factors for the implementation of the ABCC-tool in two contextually different settings.

A limitation of this study is that a selection of CFIR constructs is made. Possibly, relevant contextual factors will be missed because of this. However, evaluating the full scope of CFIR would be too time demanding. The selection was made with careful consideration of the trial design and the national context of primary care (see appendix 2) in several discussion rounds by three researchers (DC, MV, LD). Involving HCPs in the design of this study could have reduced the risk of selection bias even further. Furthermore, due to the design this research, targeted implementation strategies cannot be deployed until after the study period. In order to evaluate patient outcomes in the effectiveness trial, changes to the intervention or its implementation were not allowed during the trial to minimize their impact on effectiveness outcomes. While this approach delays supporting the implementation process, it does allow barriers and facilitators to be followed and to develop implementation strategies to those determinants that are actually in need of support. Additionally, this study does not weigh in the experiences and context of participating patients in the effectiveness trial. In order to minimize the influence of this implementation study on the effect that is measured in patients, an evaluation of patient experiences is planned to take place after finalizing the data collection in the effectiveness trial. This will enable us to study the experiences of patients after an extended period of use while maintaining the integrity of current effectiveness measurements. The effectiveness trial also imposed limitations on the eligible population and the use of the full scope of the RE-AIM framework. With only a limited number of HCPs to include in this

implementation study, evaluating reach and organizational adoption will only be possible to some extent.

Accounting for the above mentioned strengths and limitations, this study will enable to explore the implementation of the ABCC-tool in a real world primary care setting. Studying the context of HCPs strengthens our understanding of their starting perspective for implementing a novel intervention such as this care-supporting tool. It also enables identification of (potential) barriers and facilitators as well as to follow their development over time. Understanding the local implementation process and difficulties facilitates the adaptation of the intervention and the design of appropriate implementation strategies for broad implementation. As such this study protocol is a first step towards the ABCC-tool's routine use in clinical practice in Dutch primary care.

Ethics and dissemination

Ethics approval and consent

The presented study was approved by the Medical Ethics Committee of Zuyderland Hospital, Heerlen (METCZ20180131). Written informed consent is mandatory prior to participation in the study. Transcripts from the qualitative interviews will be deidentified for the privacy of the participants.

Dissemination

The results from the study in this protocol will be disseminated through publication in peer-reviewed scientific journals and conference presentations. The results from this study will be used to facilitate implementation in other practices through the development of tailored implementation strategies.

Declarations

Competing interests

The authors declare that they have no competing interests.

Author's contributions

DC, MV and LD designed the study in close collaboration with EB, LK, AG and OS. DC wrote the first version of the manuscript of this study protocol under supervision of MV and LD. All authors have read and approved the final version of the manuscript.

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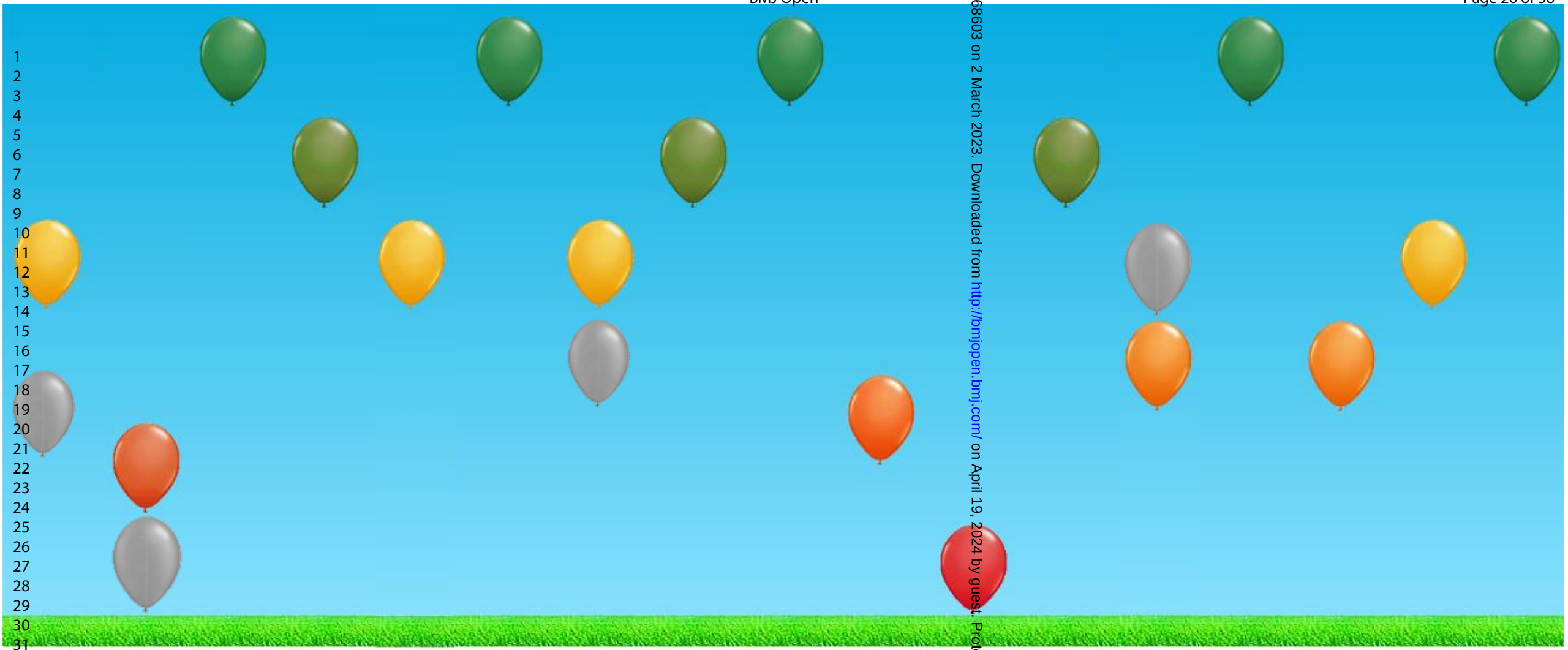
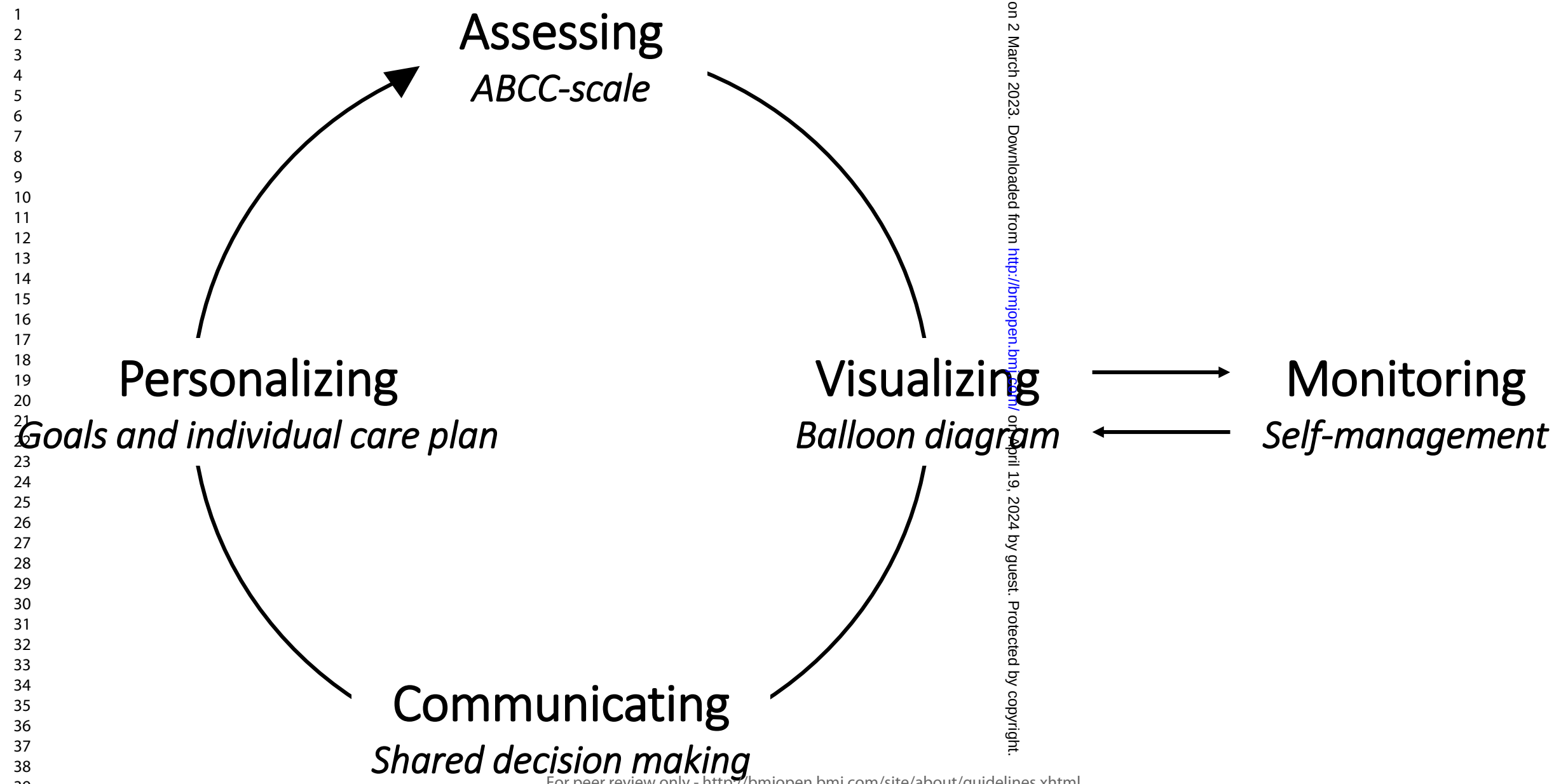
Figure 1: ABCC-tool visualization. An example of the visualization of the outcomes of the ABCC-tool, in this case for someone with COPD and T2DM. Each balloon represents a unique domain in the ABCC-tool. Green balloons indicate low burden, yellow balloons indicate moderate burden, and red balloons indicate high burden. Grey balloons indicate the score form the previous visit for comparison. A separate "questions" open field shows the additional topics or questions that the patient proposed in the questionnaire.

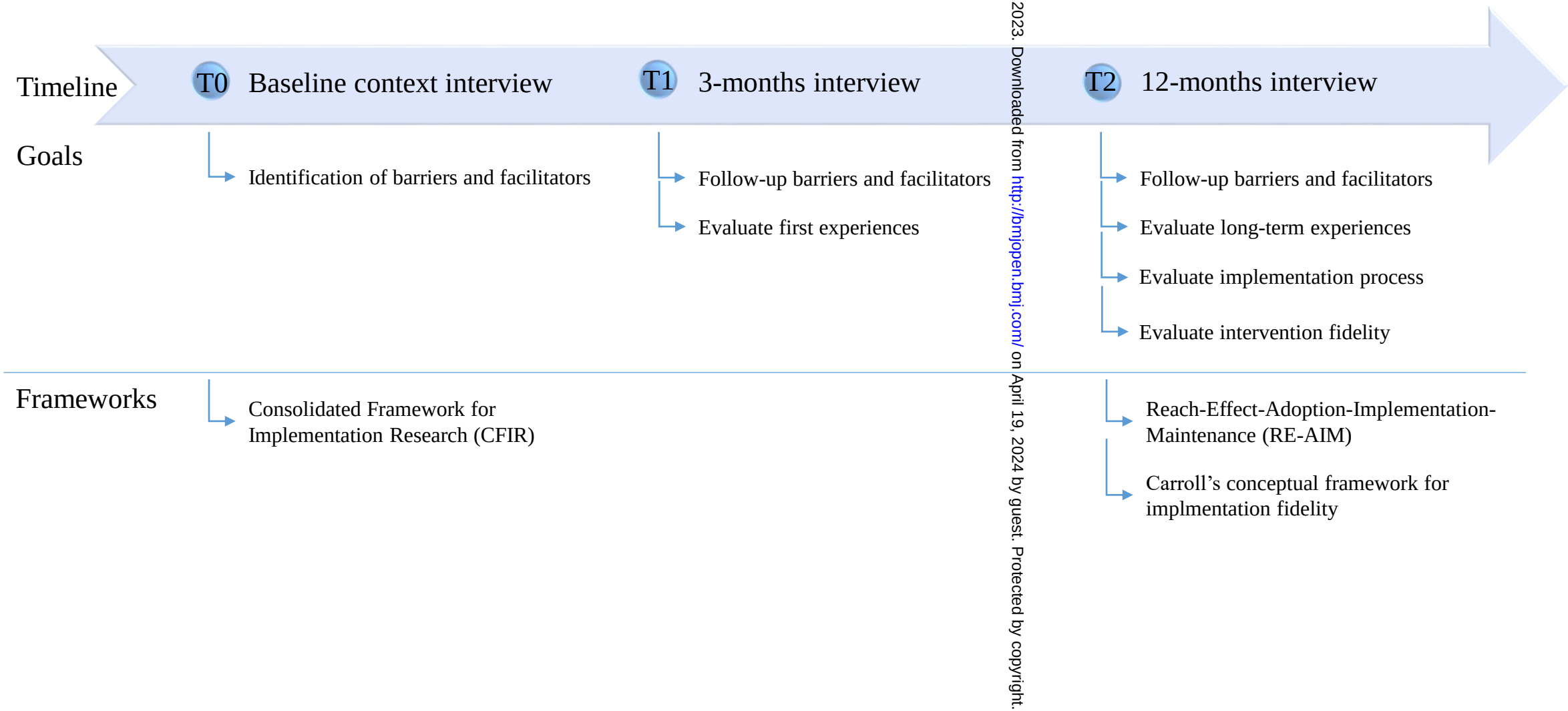
Figure 2: Process of using ABCC-tool. An overview of the cycle of using the ABCC-tool. The cycle starts at the assessing step, and then continues through the visualizing, communicating, and personalizing steps. After the initial evaluation, the visualizing step also facilitates the monitoring step because the balloons from the previous visit are presented in grey shades.

Figure 3: Overview of study design. An overview of planned interview moments, specified by the goals of the interview and used frameworks. T0 is the baseline interview prior to actual use, with T1 and T2 following after 3 and 12 months of use respectively.



Questions:





Standards for Reporting Implementation Studies: the StaRI checklist for completion

The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies (StaRI) statement. *BMJ* 2017;356:i6795

The detailed Explanation and Elaboration document, which provides the rationale and exemplar text for all these items is: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths C, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor S, for the StaRI group. Standards for Reporting Implementation Studies (StaRI). Explanation and Elaboration document. *BMJ Open* 2017 2017;7:e013318

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.	The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standardsrefers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	**1**	1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	**2**	1-2	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	**3**	3-5	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	**4**	10-11	The scientific background and rationale for the implementation strategy (including any underpinning	3-6	The scientific background and rationale for the intervention being implemented (including evidence

			theory/framework/model, how it is expected to achieve its effects and any pilot work).		about its effectiveness and how it is expected to achieve its effects).
Aims and objectives	**5**	5	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	**6**	5-6	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons.		
Context	**7**	7-8	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	**8**	7-8	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	7-8	The population targeted by the intervention and any eligibility criteria.
Description	**9**	10-11	A description of the implementation strategy	6	A description of the intervention
Sub-groups	**10**	7-8	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	**11**	11-13	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	N/A	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	**12**	11-13	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	**13**	N/A	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	**14**	10	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	**15**	13-14	Methods of analysis (with reasons for that choice)		
Sub-group analyses	**16**	13-14	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		

Results					
Characteristics	**17**	N/A	Proportion recruited and characteristics of the recipient population for the implementation strategy	N/A	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	**18**	N/A	Primary and other outcome(s) of the implementation strategy	N/A	Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	**19**	N/A	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	**20**	N/A	Resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	**21**	N/A	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/ adaptation	**22**	N/A	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	N/A	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	**23**	N/A	Contextual changes (if any) which may have affected outcomes		
Harms	**24**	N/A	All important harms or unintended effects in each group		
Discussion					
Structured discussion	**25**	14-17	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	**26**	17	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	17	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	**27**	18-19	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		

Appendix 2 Selection of CFIR constructs for the T0 interview topic guide

CFIR construct	Explanation *	Included	Reasons for not being included
Intervention characteristics			
Intervention source	Stakeholder's perception about development of de intervention (i.e. internal or external)	No	The ABCC-tool is implemented in a group of HCPs during an effectiveness trial. To maintain a comparable starting point, none of the HCPs could have participated in the development process.
Evidence strength and quality	Stakeholder's perception on the quality and validity of evidence supporting the intervention	No	The evidence supporting the ABCC-tool's desired outcomes is being gathered in the ongoing effectiveness trial. Thus, HCPs could not evaluate this at the starting point of the implementation study.
Relative Advantage	Stakeholders' perception of the advantage of implementing the intervention as opposed to another	Yes	-
Adaptability	Stakeholder's perception of the degree to which the intervention can be adapted to local needs	No	As the ABCC-tool is currently being evaluated, changes on the tool are not allowed. The goal of the study is to identify improvements, to be implemented after the study period.
Trialability	The ability to test the intervention on a small scale in the organization	No	As the implementation of the ABCC-tool takes place in a limited amount of patients (i.e. about 5 to 10 per practice), evaluating trialability within a trial seems trivial.
Complexity	The stakeholder's perceived difficulty with the intervention (e.g. duration, scope, disruptiveness, intricacy and number of required steps to use)	Yes	-
Design quality and packaging	Stakeholder's perceived excellence in how the intervention is presented	No	Evaluation of design and packaging was not included because part of the difficulty with design and packaging will come forth as an indication of complexity, while difficulty with the design will most probably come from patients, not HCPs, in this setting. Patients are interviewed separately in another study.
Cost	Costs of the intervention and costs associated with implementing the intervention	No	The ABCC-tool is free from direct costs, as the third party collaborators offer the tool freely. While indirect costs may also arise from changing the consultation, we expect that this may not be reflected in the HCPs experiences. A reflection of maintenance will be included in the T2 interview, which will include a reflection on the cost-benefit balance.
Outer setting			
Patient needs	The HCP's knowledge and priority on the patient's needs, as well as barriers and facilitators (e.g. patient-centeredness and skills of the patient)	Yes	-

Cosmopolitanism	The degree to which a network is present with other organizations	No	Though general practices are highly networked within other primary healthcare providers (i.e. such as physical therapy and psychology), the use of the ABCC-tool is possible only in the general practice.
Peer pressure	The competitive pressure to implement the intervention	No	Competition is less influential in primary care in the Netherlands as anyone is allowed free GP care. Competition may play a role in decisions at the buy-in of care between the provider and insurer, but the evidence of the ABCC-tool is not yet sufficient to influence those decisions.
External policies and incentives	A combination of all external strategies, policy and regulations that influence implementation of the intervention.	Yes	-
Inner setting			
Structural characteristics	The social characteristics of the organization (i.e. including age and size)	Yes	-
Networks and communications	The characteristics of the social network within the organization (i.e. nature and quality, and both formal and informal)	Yes	-
Culture	A combination of the norms, values and basic assumptions of the organization	Yes	-
Implementation climate	An umbrella-construct reflecting the absorptive capacity for change, receptivity, and reward for using the intervention. Sub-constructs of Implementation Climate (IC) are marked below	Yes	-
Tension for change (IC)	Stakeholder's perception of the current situation as tolerable or needing change	Yes	-
Compatibility (IC)	Stakeholder's perception of the degree of alignment of individual values with those that the intervention represents	Yes	-
Relative priority (IC)	The shared perception of importance of the intervention within the organization	Yes	-
Organizational incentives and rewards (IC)	The extrinsic incentives that result from using the intervention (e.g. goal awards, performance reviews, promotions, or stature)	No	Besides a compensation of working hours, no kind of rewards are coupled to using the ABCC-tool. Because of the strongly guideline-oriented primary care in the Netherlands, extrinsic incentives can only apply when the ABCC-tool is proven a best practice. And the evidence for that is still being gathered (i.e. effectiveness being some of that evidence).
Goals and feedback (IC)	The degree to which goals with respect to the intervention are communicated, acted upon, and feedback is given.	Yes	-

Learning climate (IC)	The stakeholders perception of whether the internal climate allows for: 1) leaders to express need for assistance and input, 2) team members to feel essential and valued, 3) individuals to feel psychologically safe, and 4) sufficient time and space for reflective thinking and evaluating	Yes	-
Readiness for implementation	An umbrella-construct reflecting the organization's commitment to implementing the intervention. Sub-constructs of Readiness for Implementation (RI) are marked below	Yes	-
Leadership engagement (RI)	Stakeholder's perception of the commitment, involvement and accountability of leaders and managers in the organization	Yes	-
Available resources (RI)	Stakeholder's perception of the resources needed for the implementation of the intervention (e.g. money, training, physical space, and time)	Yes	-
Access to knowledge and information (RI)	The stakeholder's perception of the access to digestible information about the intervention and how to incorporate it into the daily work tasks	No	HCPs received a brief document and poster on how the intervention works and how to use it in conversation. No training was provided, nor were there other experts or colleagues to discuss the intervention with because these HCPs are the first to use it. The results of this implementation study will eventually guide the development of a case-based training. However, at this phase we expected fewer experiences with the access to knowledge, and chose to leave it out for the sake of the interview duration.
Individual characteristics			
Knowledge and beliefs about the intervention	The stakeholder's individual attitudes and values with respect to the intervention, as well as familiarity with facts, truths and principles related to the intervention	Yes	
Self-efficacy	The stakeholder's individual belief in their own capabilities to execute the implementation of the intervention	Yes	
Individual stage of change	Characterization of the phase of change in which the individual is (i.e. towards a skilled, enthusiastic and sustained use)	No	Assessing the individual stage of change would invoke a more rigorous assessment, causing the total time span of the interview to fall well past 60 minutes. While acknowledging the importance of the stage of change, the selection of constructs did not include it.
Individual identification	The stakeholder's perception of their relation and commitment to their organization	Yes	

with the organization			
Other personal attributes	A broad construct containing all personal traits of the stakeholder (e.g. intellectual ability, motivation, values, competence, capacity and learning style)	Yes	
Process			
Planning	The degree to which a scheme or method for implementation is designed in advance, and the quality of these schemes	No	All process-constructs are left out of the interview for several reasons: 1) The HCPs are not likely capable to reflect on this as they are primarily involved in executing the intervention, but not in the other processes 2) General practices are mostly too small of an organization to have distinguished roles (i.e. opinion leaders, implementation leaders etc.). In most cases, this is one and the same person in a single practice. These constructs are more relevant for larger scale implementation projects (i.e. such as within an entire care group)
Engaging	An umbrella-construct reflecting the attraction and involvement of the appropriate individuals in the implementation and use of the intervention. Sub-constructs of Engagement (E) are marked below	No	
Opinion leaders (E)	The individuals in the organization that formally influence attitudes and beliefs in the organization (i.e. experts and peers)	No	
Formally appointed internal implementation leaders (E)	The individuals that are responsible for the implementation within the organization (e.g. coordinator, manager, or leader)	No	
Champions (E)	The individuals who dedicate themselves to implementing the intervention (e.g. through supporting, marketing, or overcoming resistance in the organization)	No	
External Change Agents (E)	The individuals outside of the organization who formally influence or facilitate implementation of the intervention	No	
Executing	Executing the intervention according to plan	No	
Reflecting and evaluating	Feedback about the progress and quality of the implementation, including regular debriefing about the progress	No	

Explanation and selection of CFIR constructs for the T0 interview guide. *All explanations are from the CFIR codebook, available at: https://cfirguide.org/guide/app/#/guide_select. The organization for all constructs is a general practice.

Appendix 3 Explanation of the T2 interview topic guide

Construct	Explanation
RE-AIM framework*	
Reach (not evaluated)	The absolute number/proportion and representativeness of individuals participating in the intervention as recipients (e.g. patients). This includes barriers and facilitators to participation, explanations regarding variations of participation across study sites, and reasons behind participation (or not). *This construct is not assessed in this present study because the number of participants is highly limited by the effectiveness study. . A proper evaluation of reach can therefore not be performed.*
Effectiveness	The impact of an intervention on important outcomes, such as potential negative effects, quality of life and economic outcomes. This includes the conditions and mechanisms that could lead to the effects, and explanations about the variation across study sites.
Adoption (not evaluated)	The absolute number/proportion and representativeness of individuals participating in the intervention as intervention agents (e.g. HCPs). Adoption can have multiple nested levels within an organization. This includes reasons that affect provider participation. *This construct is not assessed in this present study because the number of intervention agents is highly limited by those in the effectiveness study. A proper evaluation of adoption can therefore not be performed.*
Implementation (see fidelity)	The fidelity (adherence) to the key components of the intervention, including deviations and adaptations made and the underlying reasons. *This construct is evaluated in more detail using the fidelity framework described below.*
Maintenance	The extent to which the intervention becomes institutionalized or part of routine practice, and includes steps taken to ensure maintenance of the intervention in that particular general practice and barriers to sustained use.
Fidelity framework	
Content	The active ingredients of the intervention. The active ingredients are described below.
1) A scale measuring burden	The scale of the ABCC-tool is the first step in its five-step cycle. The scale should be completed by the patient (either digitally or with a paper-based questionnaire) and copied to the information system in case a paper-based questionnaire was used. All questions have to be answered for this step to be completed.
2) Visualization of burden	The visualization of the outcomes of the questionnaire, being the second step, is performed automatically by the information system upon clicking the "show balloon chart" button in-screen). The visualization should be clearly visible by both HCP and patient and used as guidance for the conversation topics.
3) Shared decision making	The HCPs should engage the patient to have an active role in the care conversation based on the principles of shared decision making in the third step. The shared decision making process should include: selecting balloons/domains as a topic of conversation together, exploring the burden within that domain, and opting for a personalized care plan.
4) Constructing a care plan	After the shared decision making process a personalized care plan is made in the. This care plan should be described as clearly as possible, for which we recommend the SMART-principles (40).
5) Monitoring the progress	After the patient is sent home, the fifth step of the cycle takes place: monitoring. The new assessment of burden is depicted in color, while the previous will be in grey. The HCP should compare both situations (i.e. height of the balloons) and use this information to monitor the patient's progress.
Coverage	These three constructs are more generally known and described as the dose of the intervention. The ABCC-tool should be used in all participating patients (i.e. coverage), during all check-up visits (i.e. frequency), and should take no longer than the regular available time period for a check-up (i.e. duration). The use of the ABCC-tool should be maintained throughout the study period (i.e. at least 12 months). The frequency of regular visits is dependent on the
Frequency	
Duration	

	condition (i.e. regular check-ups occur about once a year for people with COPD or asthma, and about four times a year for people with T2DM).
Constructs that did not originate from theoretical frameworks	
Experiences	The self-expressed lived experiences with working with the ABCC-tool. This construct is added to identify those aspects that have gained most attention from the HCP themselves, and which should at least be discussed.
Barriers and facilitators	The identified barriers and facilitators from the T0 and T1 interview are reflected upon again in this interview.
Training	An additional question is asked about whether training necessary for HCPs with no experience with the ABCC-tool, which aspects should be covered during a future training, to whom the training should be offered, and who should be the trainer.
Recommendation	To conclude the interview, the HCP is asked to reflect on whether they would recommend the ABCC-tool to a colleague, including the reasons behind their answer.

An overview of the frameworks used in the T2 interview, including additional questions that did not come from theoretical frameworks. * All explanation are directly from the RE-AIM website: https://www.re-aim.org/about/what-is-re-aim/ and the qualitative inquiries as suggested by the RE-AIM QUEST framework (34). ** The explanations are derived from those proposed by Carroll et al (14).