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BMJ Open 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 personalised 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 semistructured interviews throughout 12 months of use. Interviews will be audiorecorded and transcribed. Transcripts will be analysed 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.

INTRODUCTION

The shift from disease-centred care towards personalised care requires healthcare providers (HCPs) to customise care to

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 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.

individual needs and collaborate on personalised 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 personalising clinical practice. PROMs are questionnaires that measure a person's perspective on health-related outcomes such as quality of life (QoL) or well-being.² These questionnaires are used in clinical practice at an increasing rate in order to improve and guide personalised 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 visualised into a balloon chart

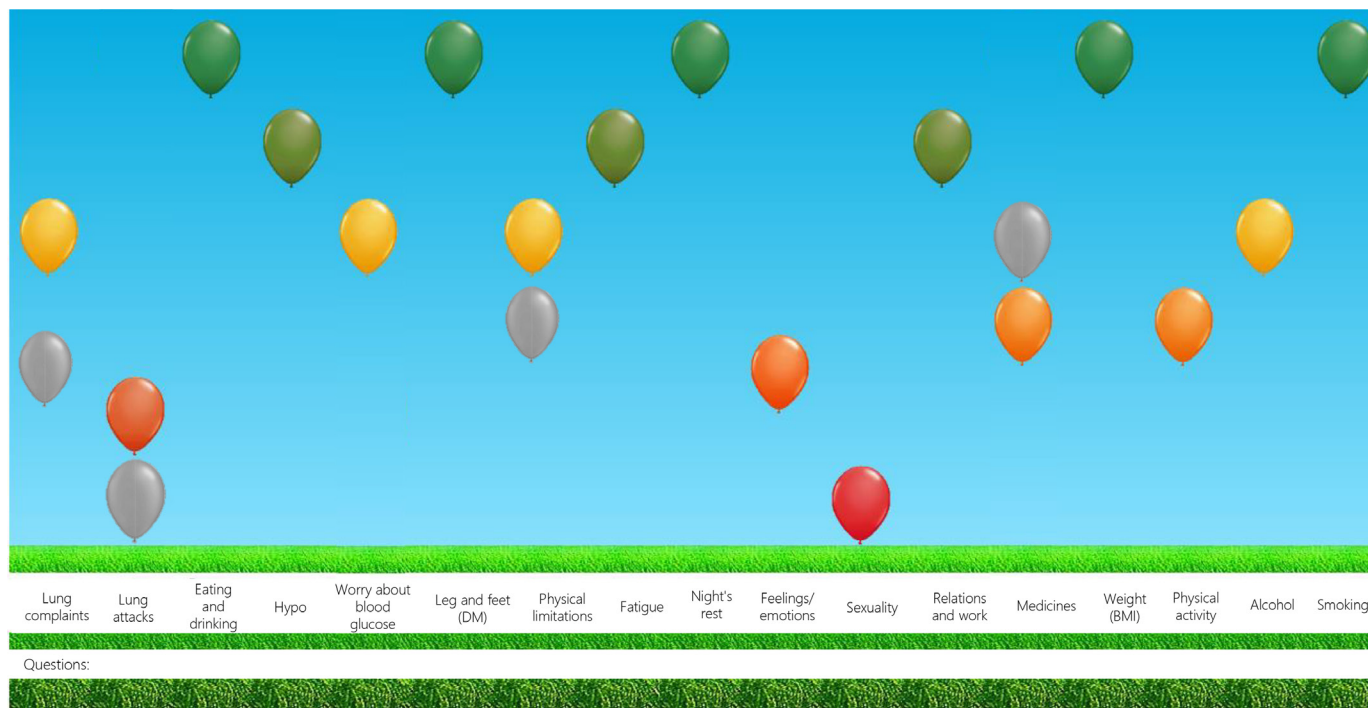


Figure 1 ABCC-tool visualisation. An example of the visualisation of the outcomes of the ABCC-tool, in this case for someone with COPD and T2DM. Each balloon represents a unique domain in the ABCC-tool. Green balloons indicate low burden, yellow balloons indicate moderate burden, and red balloons indicate high burden. Grey balloons indicate the score from the previous visit for comparison. A separate 'questions' open field shows the additional topics or questions that the patient proposed in the questionnaire. ABCC, Assessment of Burden of Chronic Conditions; COPD, chronic obstructive pulmonary disease; T2DM, type 2 diabetes mellitus.

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 (ie, the PROM), a visualisation 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 personalised 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 into 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 (ie, 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 were considered while composing this study protocol (see online supplemental appendix 1).^{15 16} This

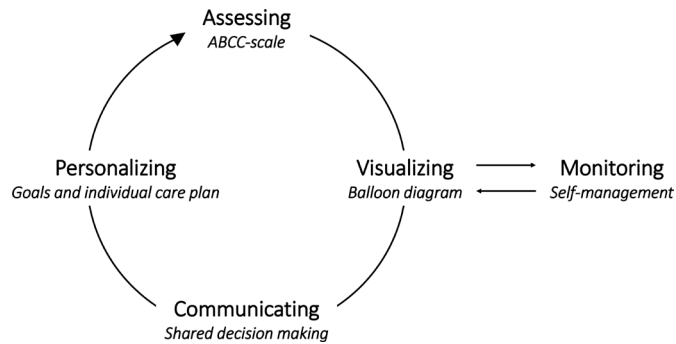


Figure 2 Process of using ABCC-tool. An overview of the cycle of using the ABCC-tool. The cycle starts at the assessing step, and then continues through the visualising, communicating and personalising steps. After the initial evaluation, the visualising step also facilitates the monitoring step because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

implementation study will be conducted alongside an effectiveness trial (details of the effectiveness-part of the study are described elsewhere⁹). 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, QoL, 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 an HCP and a patient towards a personalised 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 (ie, with different scales for people with asthma, COPD, T2DM or CHF). Second, the outcomes of the questionnaire are digitally transformed into a balloon chart visualisation (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. On 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 visualised in the previous consultation are presented in grey while displaying the current balloons in colour (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 (ie, MicroHIS) or an Integrated Care Information System (ie, 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 (eg, both HCP and patient can access the tool) and use of the ABCC-tool (eg, 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 3 hours at an average practice nurse salary rate will be compensated to the practice in which they work.

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 GPs 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 centre (ie, single or multiple GP's collaborating with other primary care providers). GPs 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 (eg, pulmonary disease, T2DM, cardiovascular disease or a combination) or mental disease to a varying degree of independence (ie, practice nurses are supervised by GPs whereas nurse practitioners are independent HCPs).²⁰

**Box 1 Care groups in the Netherlands**

A care group is a legal body in the Dutch healthcare system, in which multiple healthcare providers in primary care (ie, most often a certain geographical region) are organised.⁴⁰ Care groups in the Netherlands negotiate payment with health insurers and account for several organisational aspects of care. In this study, the care group (in Dutch: Zorg In Ontwikkeling) facilitates care provided by general practitioners, practice nurses and nurse practitioners in the south-eastern region of the Netherlands (ie, the province of Limburg) centrally.

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 (ie, 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}

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 3 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 3 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 Reach-Effect-Adoption-Implementation-Maintenance (RE-AIM) and fidelity frameworks. Participant will remain the same throughout the study period (ie, three consecutive interviews per participant). One researcher (DC) will perform all

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	<ul style="list-style-type: none"> ▶ Patient completes questionnaire on paper ▶ HCP copies answers to the third party digital environment 	<ul style="list-style-type: none"> ▶ Patient completes the questionnaire digitally in patient environment (by phone or personal computer) ▶ Completed questionnaires are automatically presented in MediX
Visualising burden	<ul style="list-style-type: none"> ▶ Balloons are presented in third party digital HCP environment ▶ Patients cannot view balloons at home 	<ul style="list-style-type: none"> ▶ 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. ABCC, Assessment of Burden of Chronic Conditions; HCPs, healthcare providers.		

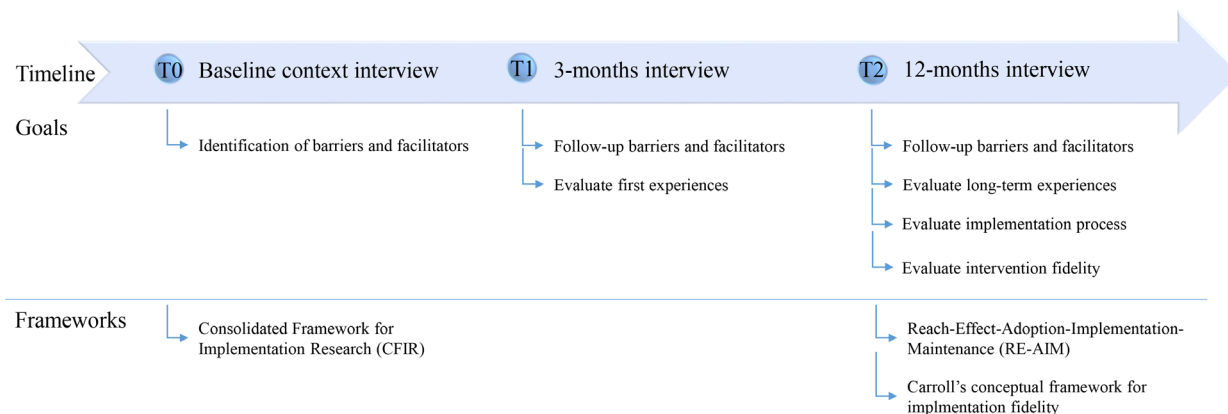


Figure 3 Overview of study design. An overview of planned interview moments, specified by the goals of the interview and used frameworks. T0 is the baseline interview prior to actual use, with T1 and T2 following after 3 and 12 months of use respectively.

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.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 per group are estimated to observe theoretical data saturation and to allow for transferability of the results.^{28 29}

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 programme was previously identified a barrier to the implementation of the ABCC-tool's predecessor, the Assessment of Burden of COPD tool^{29–31} (tailoring strategies from the Expert Recommendations for Implementing Change (ERIC)^{32 33}). 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 (ie, development and distribution of educational materials from ERIC).^{32 33} 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 (ie, build a coalition from ERIC).^{32 33} 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 (ie, provide local technical assistance from ERIC).^{32 33} 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 vs MediX-users). To minimise 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 (ie, 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) and (2) implementation outcomes.

Participant demographics will be collected regarding: practice size, type of practice (GP practice or medical centre), experience using the intervention's predecessor, age, sex, education (higher education, vocational education as either nurse or doctor's assistant), function (GP, nurse practitioner or practice nurse), target population (COPD, asthma, T2DM, heart failure or a combination) and an estimate of the target population's socioeconomic 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.²⁶ CFIR is a determinant framework to assess the presence



of barriers or facilitators of study participants within their organisation, 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 (ie, 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 minimise the time burden of the interview on HCPs to a maximum of 60 min 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 and LvD) 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 online supplemental 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 RE-AIM framework.^{34–36} 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, QoL 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.*^{14,37} In this framework, fidelity is characterised 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 min 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 for the process evaluation is presented in online supplemental appendix 3.

Data analyses

All interviews will be audiorecorded, transcribed verbatim at literatim and anonymised. 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 (ie, 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 3 months of practice by means of phenomenology.³⁸

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 analysed by one researcher (DC) and discussed with another researcher (MV), on disagreement a third researcher (LvD) will decide. All data will be analysed 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 (ie, the interviews at T2 contain questions on the two frameworks, an overview of which is presented in online supplemental 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 HCPs were involved as an expert group during the development

of the 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 (ie, 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 (ie, recipients of the intervention) as well as studying the application and context of HCPs (ie, providers of the intervention).³⁹ 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 (ie, through experience or changing conditions) and new ones may arise. Alternatively, facilitators may also appear only as a temporary factor (ie, 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 ERIC-tool.^{32 33} 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 organisation 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 online supplemental appendix 2) in several discussion rounds by three researchers (DC, MV and LvD). Involving HCPs in the design of this study could have reduced the risk of selection bias even further. Furthermore, due to the design of 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 minimise 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 for 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 minimise 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 finalising 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 organisational 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.

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