

# BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email [info.bmjopen@bmj.com](mailto:info.bmjopen@bmj.com)

# 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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-068603
Article Type:	Protocol
Date Submitted by the Author:	26-Sep-2022
Complete List of Authors:	<p>Claessens, Danny; Maastricht University, Department of Family Medicine Vervloet, Marcia; Netherlands Institute for Health Services Research Boudewijns, Esther Adriana; Maastricht University Faculty of Health Medicine and Life Sciences</p> <p>Keijsers, Lotte C.E.M. ; Maastricht University Faculty of Health Medicine and Life Sciences</p> <p>Gidding-Slok, Annerika; Maastricht University, CAPHRI School for Public Health and Primary care, Department of Family Medicine</p> <p>van Schayck, Onno; Maastricht University, HAG</p> <p>van Dijk, Liset; NIVEL Netherlands institute for health services research</p>
Keywords:	PRIMARY CARE, DIABETES & ENDOCRINOLOGY, Change management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Asthma < THORACIC MEDICINE, Chronic airways disease < THORACIC MEDICINE

SCHOLARONE™  
Manuscripts

1  
2  
3 **Understanding the healthcare providers' perspective for bringing the Assessment of**  
4 **Burden of Chronic Conditions tool to practice: a protocol for an implementation study**  
5  
6  
7  
8  
9

10 Danny Claessens<sup>1</sup>, Marcia Vervloet<sup>2</sup>, Esther A. Boudewijns<sup>1</sup>, Lotte C.E.M. Keijsers<sup>1</sup>, Annerika  
11 H.M. Gidding-Slok<sup>1</sup>, Onno C.P. van Schayck<sup>1</sup>, Liset van Dijk<sup>2,3</sup>  
12  
13  
14  
15  
16

17 <sup>1</sup> Department of Family Medicine, Care and Public Health Research Institute (CAPHRI),  
18 Maastricht University, Maastricht, the Netherlands  
19

20 <sup>2</sup> Nivel, Netherlands Institute for Health Services Research, Utrecht, the Netherlands  
21

22 <sup>3</sup> Department of Pharmacotherapy, -Epidemiology and -Economics, Groningen Research  
23 Institute of Pharmacy, Faculty of Science and Engineering, University of Groningen,  
24 Groningen, the Netherlands  
25  
26  
27  
28  
29

30  
31  
32  
33 Corresponding author: Danny Claessens  
34

35 P.O. Box 616, 6200 MD Maastricht, the Netherlands  
36

37 Phone: +3143-3882836  
38

39 [danny.claessens@maastrichtuniversity.nl](mailto:danny.claessens@maastrichtuniversity.nl)  
40  
41  
42

43 Word count: 3771  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## 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

1  
2  
3 in the study. The results from the study in this protocol will be disseminated through publication  
4  
5 in peer-reviewed scientific journals and conference presentations.  
6  
7  
8  
9

10 **Key words:** Assessment of Burden of Chronic Conditions (ABCC-) tool, burden of disease,  
11 patient-centered care, implementation, context, Consolidated Framework for Implementation  
12 Research (CFIR), process, RE-AIM, fidelity framework, general practice, primary care  
13  
14  
15  
16  
17  
18

### 19 **Strengths and limitations of this study**

- 21 • Implementation-effectiveness hybrid studies enable the combination of quantitative and  
22 qualitative outcomes, and therefore a better understanding of the complex reality of  
23 implementing novel interventions. These studies, however, are rarely conducted in  
24 primary care.  
25  
26  
27  
28  
29
- 30 • Studying the determinants of implementation, implementation fidelity and  
31 implementation outcomes alongside an effectiveness trial bridges the gap between  
32 research and practice.  
33  
34  
35  
36  
37
- 38 • The temporal design of this study enables to understand the development of identified  
39 barriers and facilitators to implementation over time.  
40  
41
- 42 • A limitation of this study is that the hybrid nature of this design does not allow for the  
43 deployment or alteration of implementation strategies during the effectiveness study.  
44  
45  
46
- 47 • Patients' experiences are not studied in this presented study, but will be evaluated in a  
48 separate study.  
49  
50  
51  
52  
53  
54  
55  
56

### 57 **Introduction**

58  
59  
60

1  
2  
3 The shift from disease-centered care towards personalized care requires from healthcare  
4 providers (HCPs) to customize care to individual needs and collaborate on personalized  
5 treatment goals (1). This, however, demands from the HCP to understand each individual's  
6 experience of health or life in general. Patient Reported Outcome Measures (PROMs) can help  
7 HCPs to grasp a person's experience, and thus can make a difference when personalizing  
8 clinical practice. PROMs are questionnaires that measure a person's perspective on health-  
9 related outcomes such as quality of life (QoL) or wellbeing (2). These questionnaires are used  
10 in clinical practice at an increasing rate in order to improve and guide personalized care for  
11 people with various chronic conditions (3-5). The Assessment of Burden of Chronic Conditions  
12 (ABCC-) tool includes a PROM of which the outcomes are visualized into a balloon chart for  
13 easy comprehension. The tool is developed to guide care conversations towards the personal  
14 experienced burden of someone with Chronic Obstructive Pulmonary Disease (COPD), asthma,  
15 type 2 Diabetes Mellitus (T2DM), and/or chronic heart failure (CHF) (6, 7). The tool consists  
16 of a scale that validly and reliably measures a patient's experienced burden (i.e. the PROM), a  
17 visualization of the outcomes of that scale (figure 1), and domain-specific treatment advice  
18 based on the outcome of the scale (6-8). As such, the ABCC-tool enables HCP and patient to  
19 address the experienced burden and to formulate personalized goals for the domains of choice.  
20 The tool is now being evaluated for its effectiveness in improving patients' experienced quality  
21 of care (9). The transition of the ABCC-tool from the scientific development and evaluation  
22 phase towards routine clinical application is driven by implementation processes (4, 5, 10).  
23 Understanding these processes is key in understanding its effects as well as facilitating large-  
24 scale implementation of the ABCC-tool.  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

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

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

13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28 In order to understand the implementation of the ABCC-tool in general practices, the underlying  
29 determinants and process to implementation need to be understood. When these are understood,  
30 they can be used for improvements to the ABCC-tool to facilitate implementation at a larger  
31 scale. The aim of this paper is therefore to describe a study protocol for the assessment of 1)  
32 the barriers and facilitators for HCPs to implement the ABCC-tool, 2) the process of  
33 implementing the ABCC-tool, and 3) the fidelity of the ABCC-tool in general practices in the  
34 Netherlands.

### 35 36 37 38 39 40 41 42 43 44 45 46 47 **Methods and analysis**

48  
49 The Standards for Reporting Implementation Studies (StaRI) were considered while composing  
50 this study protocol (see appendix 1) (15, 16). This implementation study will be conducted  
51 alongside an effectiveness trial (details of the effectiveness-part of the study are described  
52 elsewhere (9)). In short, a pragmatic clustered quasi-experimental study will be conducted in  
53 general practices in the Netherlands evaluating the ABCC-tool on patients' experience of  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 quality of care, quality of life, patient activation and healthcare costs. Patients from 18  
4 intervention practices and 18 control practices will be followed for 18 months of using the  
5 ABCC-tool. HCPs will act as interventionists using the ABCC-tool in the effectiveness trial,  
6  
7 while being the participants in the implementation study.  
8  
9  
10  
11  
12  
13

### 14 The ABCC-tool

15  
16 The ABCC-tool is developed to guide the conversation between a HCP and a patient towards a  
17 personalized care plan, by integrating experienced burden in the conversation (6). The cycle of  
18 using the ABCC-tool contains several steps (figure 2). First, the patient completes a  
19 questionnaire regarding their experienced burden (i.e. with different scales for people with  
20 asthma, COPD, T2DM or CHF). Second, the outcomes of the questionnaire are digitally  
21 transformed into a balloon chart visualization (figure 1) (6). Third, both the HCP and patient  
22 discuss the presented balloons and pick one or more balloons of the patients choosing to  
23 elaborate on during that particular consultation. Upon clicking on one of the balloons,  
24 guideline-based treatment advice is presented as an in-screen pop-up. The fourth step in the  
25 cycle is to formulate a specific care goal and plan, fueled by the treatment advice and the  
26 possibilities and chances in the patient's context. Fifth, during the next consultation, the  
27 balloons that were visualized in the previous consultation are presented in grey while displaying  
28 the current balloons in color (see figure 1). Displaying the differences in this way allows for  
29 easy monitoring of the progress of experienced burden by the HCP and patient. The treatment  
30 advice that is used to build the personalized care plan also refers to using other eHealth  
31 applications, in between consultations with a GP or nurse, to achieve lifestyle goals. E-health  
32 applications can extend support to the home environment, while HCP consultations cover only  
33 a fraction of the time a patient spends to manage their own health (17). Therefore, the current  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60



1  
2  
3 use of E-health applications will be included in the interview guide. The ABCC-tool will be  
4  
5 used during each routine consultation as described above.  
6  
7  
8  
9

### 10 Population and recruitment

11  
12 The target population in this study is HCPs in primary care, which will be recruited from the  
13  
14 intervention arm of the effectiveness trial. All HCPs work in general practices in the  
15  
16 Netherlands as general practitioner (GP), practice nurse, or nurse practitioner. For this study,  
17  
18 HCPs are only eligible if they provided care for people with COPD, asthma, T2DM or CHF.  
19  
20 These HCPs use either a specific General Practice Information System (i.e. MicroHIS) or an  
21  
22 Integrated Care Information System (i.e. MediX) in which the ABCC-tool was technically  
23  
24 integrated. Coding and analyses will be performed separately for two subgroups of participants  
25  
26 based on whether they used either MicroHIS or MediX to use the ABCC-tool. The reason for  
27  
28 this is that differences between these information systems exist in their users' context, access  
29  
30 to the ABCC-tool (e.g. both HCP and patient can access the tool), and use of the ABCC-tool  
31  
32 (e.g. patients complete the questionnaire digitally). Particularly, HCPs that use MediX are  
33  
34 grouped in the same care group named ZIO (see box 1), while MicroHIS users are all individual  
35  
36 HCPs. Studying these groups separately allows for the study of implementation in two distinct  
37  
38 real-world contexts. A detailed description of these differences is provided in table 1. Because  
39  
40 participating HCPs are interviewed during office hours, a total of three hours at an average  
41  
42 practice nurse salary rate will be compensated to the practice in which they work.  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

**Table 1: Description of distinctive subgroups.**

	<b>Individual HCPs</b>	<b>HCPs from ZIO care group</b>
<b>Context</b>		
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
<b>Access to ABCC-tool</b>		
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
<b>Using ABCC-tool</b>		
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.

1  
2  
3 single or multiple GP's collaborating with other primary care providers). General practitioners  
4 provide, as the name implies, care to people with any condition. Practice nurses and nurse  
5 practitioners in the Netherlands provide care for people with chronic somatic conditions (e.g.  
6 pulmonary disease, T2DM, cardiovascular disease, or a combination) or mental disease to a  
7 varying degree of independence (i.e. practice nurses are supervised by general practitioners  
8 whereas nurse practitioners are independent HCPs) (19). General practice-provided care in the  
9 Netherlands is strongly guided by the guidelines of the Dutch College of General Practitioners.  
10 As part of these guidelines, people with chronic conditions regularly visit their HCP when their  
11 condition is stable (i.e. once or twice a year for people with asthma or COPD, and four times a  
12 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

1  
2  
3 description of the context will be used to identify barriers and facilitators to implementation.  
4  
5 After three months (T1), a follow-up interview will be held to reflect on the first experiences  
6  
7 with the ABCC-tool and the status of the identified barriers and facilitators from T0. If any  
8  
9 other barriers or facilitators arise in the three months of use, they will be added to the list of  
10  
11 barriers and facilitators that will be discussed during the next interview after 12 months. At T2,  
12  
13 also a process evaluation of experiences, uptake into routine practice, and fidelity of the ABCC-  
14  
15 tool will take place using the RE-AIM and fidelity frameworks. One researcher (DC) will  
16  
17 perform all interviews to maintain stability in the interaction between the researcher and  
18  
19 participant.  
20  
21  
22  
23  
24  
25

### 26 Sample size

27  
28 Participants in this implementation study will be a subsample of the participating HCPs in the  
29  
30 effectiveness trial. Empirically, qualitative data saturation is reached on average after 12-13  
31  
32 interviews (27). In a comparable qualitative evaluation of the ABCC-tool's predecessor (the  
33  
34 ABC-tool specific for COPD), 9 out of 15 participants were sufficient to observe theoretical  
35  
36 data saturation in a similarly homogeneous population. Therefore, a maximum of 15  
37  
38 participants are estimated to observe theoretical data saturation and to allow for transferability  
39  
40 of the results (28, 29).  
41  
42  
43  
44  
45  
46

### 47 Implementation strategy

48  
49 The ABCC-tool is implemented as an incorporated tool in the information systems that HCPs  
50  
51 use. It is implemented in the same information systems as its predecessor, the Assessment of  
52  
53 Burden of COPD tool (29-31). Prior experience of the HCP with this predecessor will be  
54  
55 allowed for the HCP, but not for the patients who participate in the effectiveness trial.  
56  
57 Regardless of prior knowledge, all HCPs will receive a document and an overview poster with  
58  
59  
60

1  
2  
3 information on how to use the ABCC-tool, an explanation video presented by the researchers  
4 (accessible only with a specific weblink), and the ABCC-questionnaires for all conditions (i.e.  
5 COPD, asthma, T2DM, and CHF) as well as all possible combinations. HCPs will not be  
6 physically or digitally trained to use the ABCC-tool. However, they may have had training in  
7 the use of its predecessor. Whether participants have had training and/or experience will be  
8 asked during the first interview and will be included in the description of the context. Additional  
9 to the strategy described above, HCPs that use the Integrated Care Information System have  
10 more support during the trial. This support is primarily provided by staff from the care group  
11 and staff from the patient platform, and concerned recruitment of patients for the effectiveness  
12 trial and technical support. Researchers join in monthly meetings with the care group and  
13 patient platform staff to evaluate and assist in the implementation process. This additional  
14 support by the care group and patient platform justifies having two subgroups of participants in  
15 the analyses (individual HCPs versus HCPs from ZIO care group). To minimize the impact of  
16 the implementation study on the outcomes of the effectiveness study, all identified  
17 improvements will be implemented after the trial period. Only problems that would lead to the  
18 HCP not being able to use the ABCC-tool (i.e. technical errors) will be tackled during the study  
19 period.  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44

#### 45 Implementation outcomes

46 The implementation outcomes of this study are: 1) the barriers and facilitators for HCPs to  
47 implement the ABCC-tool, 2) the process of implementing the ABCC-tool, and 3) the fidelity  
48 of the ABCC-tool in general practices in the Netherlands. At the beginning of the study, the  
49 barriers and facilitators to implementing the ABCC-tool will be identified from the context of  
50 the participating HCPs using the CFIR (26). CFIR is a determinant framework to assess the  
51 presence of barriers or facilitators of study participants within their organization, and is often  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 used for studying the implementation of a PROM (or in this case a tool containing a PROM)  
4  
5 (4, 11). CFIR defines five domains (i.e. intervention characteristics, inner setting, outer setting,  
6  
7 individual characteristics, and process) containing 39 constructs that are known to influence  
8  
9 implementation (26). The CFIR constructs are used to compose an interview guide that targets  
10  
11 all constructs that are expected to be of influence on the implementation of the ABCC-tool in  
12  
13 general practices in the Netherlands. A selection of CFIR constructs is made in order to  
14  
15 minimize the time burden of the interview on HCPs to a maximum of 60 minutes while still  
16  
17 focusing on the constructs that seem most relevant a priori. An overview of CFIR constructs  
18  
19 and the choices whether or not to include them in the interview guide are presented in appendix  
20  
21  
22  
23  
24 2. Identified barriers and facilitators will be followed up on during the two sequential interviews  
25  
26 to evaluate how these barriers and facilitators are managed during the study period. HCPs will  
27  
28 also be asked for any additional barriers and facilitators that are experienced after the first  
29  
30 interview.  
31

32  
33  
34  
35 The Reach-Effectiveness-Adoption-Implementation-Maintenance (RE-AIM) framework will  
36  
37 be used to evaluate the implementation process and will be assessed qualitatively (32-34).  
38  
39 Reach will only be limitedly assessed because HCPs are instructed to recruit 10 eligible patients  
40  
41 to participate in the study, and as such Reach is predetermined. The Effectiveness of the ABCC-  
42  
43 tool will be evaluated as whether HCPs notice any influence of the ABCC-tool on patients,  
44  
45 specifically in terms of quality of care, quality of life, or the level of active involvement in the  
46  
47 care process. Objective effectiveness will not be evaluated in this implementation study.  
48  
49 Adoption will be evaluated as the extent to which HCPs integrated the ABCC-tool into their  
50  
51 routine practice. This includes whether the tool is being used by the GP, nurse practitioner and  
52  
53 practice nurse. The Implementation domain of the RE-AIM framework constitutes fidelity, and  
54  
55 will be evaluated in more depth using a fidelity framework (described below). Maintenance will  
56  
57  
58  
59  
60

1  
2  
3 be evaluated as how HCPs are expecting to continue working with the ABCC-tool, how they  
4 see the future of the ABCC-tool in their practice, and whether steps are taken to actually  
5 maintain the use of the ABCC-tool.  
6  
7  
8  
9

10  
11  
12 Implementation fidelity refers to the adherence to the intervention as it is intended and will be  
13 evaluated using the framework for implementation fidelity by Carroll et. al. (14, 35). In this  
14 framework, fidelity is characterized as adherence to the intervention at four levels: content,  
15 coverage, frequency and duration. In order to adequately evaluate adherence to content, the  
16 ABCC-tool is described for all steps in the cycle of its use (figure 2). Evaluation of adherence  
17 to the ABCC-tool content will focus on how HCPs have used each separate step in this cycle,  
18 and whether this is performed as intended. The coverage of using the ABCC-tool will be  
19 evaluated as whether the tool was used in all participating patients. The frequency of use will  
20 be evaluated by whether the ABCC-tool is used in each regular visit of the patient, for at least  
21 12 months. The in-consult duration of using the ABCC-tool is intended to be within the regular  
22 time for a consultation by a nurse practitioner, which is 20-30 minutes in the Netherlands. The  
23 time spent on the ABCC-tool will be evaluated qualitatively in order to assess whether this fell  
24 within this time frame and/or whether this was acceptable to the HCP. In the case that the use  
25 of the ABCC-tool is not as intended, reasons for this deviation will be explored. An interview  
26 topic guide of the process evaluation is presented in appendix 3.  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48

#### 49 Data analyses

50  
51 All interviews will be audio-recorded, transcribed verbatim at literatim and anonymized. All  
52 interviews will be independently coded by two researchers. The T0 interview will be primarily  
53 processed using deductive coding according to the constructs of the CFIR. After this step,  
54 inductive coding will be applied to identify relevant factors that were not described in the CFIR  
55  
56  
57  
58  
59  
60

1  
2  
3 (i.e. these codes will be added to our framework for understanding HCPs in this particular  
4 context). The T1 interview will be completely processed using inductive coding. The T2  
5 interview will be processed using deductive coding according to the domains that are  
6 formulated by the RE-AIM and fidelity frameworks. The data will be analyzed by one  
7 researcher and discussed with another researcher, upon disagreement a third researcher will  
8 decide. All data will be analyzed from a constructivist/interpretivist research paradigm, where  
9 understanding the subjective experience of HCPs is the main focus. As the T0 interview will be  
10 used to describe participants' context using the CFIR, a content analysis will be performed on  
11 the T0 interview to identify relevant contextual factors at play. From these contextual factors  
12 barriers and facilitators will be identified. As no theoretical framework is used for the T1  
13 interview, a thematic analysis of the T1 interview will identify the themes that represent the  
14 lived experience of HCPs after three months of practice by means of phenomenology (36). As  
15 the T2 interview mainly includes personal experiences, a thematic analysis of the T2 interview  
16 will be performed to identify relevant themes within the boundaries of both frameworks (i.e.  
17 the interviews at T2 contain questions on the two frameworks, an overview of which is  
18 presented in appendix 3). By means of phenomenology, the experiences of using and  
19 implementing the ABCC-tool will be evaluated.  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44

#### 45 Patient and public involvement statement

46 Patients and patient advocacy groups, as well as healthcare providers (HCPs), were involved as  
47 an expert group from the development of the Assessment of Burden of Chronic Conditions  
48 (ABCC-)tool, the main intervention in this study protocol. HCPs or patients were not directly  
49 involved in the design or conduct of this protocol.  
50  
51  
52  
53  
54  
55  
56  
57

#### 58 **Discussion**



1  
2  
3 The ABCC-tool is developed by, with, and for HCPs and people with chronic conditions (i.e.  
4 COPD, asthma, T2DM, and CHF). Understanding their perspective and experiences enables us  
5  
6 to fully adapt the tool to meet their requirements and needs in clinical practice. The other way  
7  
8 around, understanding how the ABCC-tool is used and implemented in a specific context,  
9  
10 enables us to facilitate implementation in other settings. Understanding the extent to which  
11  
12 HCPs have implemented the ABCC-tool in their routine practice, and which barriers and  
13  
14 facilitators hinder or stimulate this, helps to identify how HCPs can optimally be supported in  
15  
16 the implementation process. Lastly, knowing how the ABCC-tool is used and the reasons for  
17  
18 deviations from the intended use, helps us to understand whether the ABCC-tool requires  
19  
20 adjustments to local settings or whether specific training is necessary.  
21  
22  
23  
24  
25  
26  
27

28 This study protocol describes an implementation study alongside an effectiveness trial. The  
29  
30 major strength of the study lays in the hybrid nature of measuring effects in patients (i.e.  
31  
32 recipients of the intervention) as well as studying the application and context of HCPs (i.e.  
33  
34 providers of the intervention) (37). Another strength of this study design is the follow-up on  
35  
36 contextual factors to the implementation of the ABCC-tool. This temporal design enables us to  
37  
38 understand the development of barriers and facilitators over an extended period of use of the  
39  
40 ABCC-tool. Possibly, some barriers may be solved by the passing of time (i.e. through  
41  
42 experience or changing conditions) and new ones may arise. Alternatively, facilitators may also  
43  
44 appear only as a temporary factor (i.e. only facilitating at the start). The use of the well-studied  
45  
46 frameworks of CFIR, RE-AIM and the Fidelity framework from Carroll et al. strengthens the  
47  
48 observations made during this study. The use of the CFIR additionally enables the selection of  
49  
50 potential implementation strategies to resolve the identified barriers and facilitators through the  
51  
52 Expert Recommendation for Implementing Change (ERIC-) tool (38, 39). These strategies are  
53  
54 mapped on CFIR constructs to facilitate choosing ideal implementation strategies, though a  
55  
56  
57  
58  
59  
60

1  
2  
3 best-fit strategy should always match the local context. Lastly, studying the implementation in  
4  
5 two contextually different groups enables us to empirically describe the similarities and  
6  
7 differences between the two groups. The fact that HCPs from one group have a different  
8  
9 organization of care and access to the intervention makes uniform conclusions rather difficult.  
10  
11  
12 However, implementation is always subject to local context and supports a case-by-case  
13  
14 approach. The results from this implementation study enable us to describe not one, but two  
15  
16 contextual cases for implementation and study the differences and similarities between those  
17  
18 contexts.  
19

20  
21 A limitation of this study is that a selection of CFIR constructs is made. Possibly, relevant  
22  
23 contextual factors will be missed because of this. However, evaluating the full scope of CFIR  
24  
25 would be too time demanding. The selection was made with careful consideration of the trial  
26  
27 design and the national context of primary care (see appendix 2) in several discussion rounds  
28  
29 by three researchers (DC, MV, LD). Furthermore, due to the hybrid nature of this research,  
30  
31 implementation strategies cannot be deployed until after the study period. In order to evaluate  
32  
33 patient outcomes in the effectiveness trial, changes to the intervention or its implementation  
34  
35 were not allowed during the trial. While this approach delays supporting the implementation  
36  
37 process, it does allow barriers and facilitators to be followed and to develop implementation  
38  
39 strategies to those determinants that are actually in need of support. Additionally, this study  
40  
41 does not weigh in the experiences and context of participating patients in the effectiveness trial.  
42  
43  
44 In order to minimize the influence of this implementation study on the effect that is measured  
45  
46 in patients, an evaluation of patient experiences is planned to take place after finalizing the data  
47  
48 collection in the effectiveness trial. This will enable us to study the experiences of patients after  
49  
50 an extended period of use while maintaining the integrity of current effectiveness  
51  
52 measurements. The effectiveness trial also imposed limitations on the eligible population and  
53  
54 the use of the full scope of the RE-AIM framework. With only a limited number of HCPs to  
55  
56  
57  
58  
59  
60

1  
2  
3 include in this implementation study, evaluating reach and organizational adoption will only be  
4 possible to some extent.  
5  
6  
7  
8  
9

10 Accounting for the above mentioned strengths and limitations, this study will enable to explore  
11 the implementation of the ABCC-tool in a real world primary care setting. Studying the context  
12 of HCPs strengthens our understanding of their starting perspective for implementing a novel  
13 intervention such as this care-supporting tool. It also enables identification of (potential)  
14 barriers and facilitators as well as to follow their development over time. Understanding the  
15 local implementation process and difficulties facilitates the adaptation of the intervention and  
16 the design of appropriate implementation strategies for broad implementation. As such this  
17 study protocol is a first step towards the ABCC-tool's routine use in clinical practice in Dutch  
18 primary care.  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32

### 33 **Ethics and dissemination**

#### 34 *Ethics approval and consent*

35  
36  
37 The presented study was approved by the Medical Ethics Committee of Zuyderland Hospital,  
38 Heerlen (METCZ20180131). Written informed consent prior is mandatory prior to participation  
39 in the study. Transcripts from the qualitative interviews will be deidentified for the privacy of  
40 the participants.  
41  
42  
43  
44  
45  
46  
47  
48

#### 49 *Dissemination*

50  
51 The results from the study in this protocol will be disseminated through publication in peer-  
52 reviewed scientific journals and conference presentations. The participants of this study will be  
53 able to continue using the ABCC-tool after the study ends while the results from this study will  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 be used to facilitate implementation in other practices through the development of tailored  
4  
5 implementation strategies.  
6  
7  
8  
9

## 10 **Declarations**

### 11 *Competing interests*

12  
13  
14 The authors declare that they have no competing interests.  
15  
16  
17

### 18 *Author's contributions*

19  
20 DC, MV and LD designed the study in close collaboration with EB, LK, AG and OS. DC wrote  
21  
22 the first version of the manuscript of this study protocol under supervision of MV and LD. All  
23  
24 authors have read and approved the final version of the manuscript.  
25  
26  
27  
28  
29

### 30 *Funding*

31  
32 The work was supported by the Netherlands Organisation for Health Research and  
33  
34 Development, grant number 104006001. The funding organization had no influence on the  
35  
36 design or execution of the study nor writing the manuscript or the decision to publish.  
37  
38  
39  
40  
41

### 42 *Acknowledgements*

43  
44 We would like to express our gratitude to Leah Zullig, Hayden Bosworth and all colleagues at  
45  
46 the Duke Department of Population Health Sciences for their critical reflection on our study  
47  
48 design and allowing us to learn from their experience in the field of implementation sciences.  
49  
50  
51  
52

## 53 **References**

- 54  
55  
56 1. Reuben DB, Sinsky CA. From Transactional Tasks to Personalized Care: A New  
57  
58 Vision of Physicians' Roles. *Ann Fam Med*. 2018;16(2):168-9.  
59  
60

- 1  
2  
3 2. Dawson J, Doll H, Fitzpatrick R, Jenkinson C, Carr AJ. The routine use of patient  
4 reported outcome measures in healthcare settings. *BMJ*. 2010;340:c186.
- 5  
6  
7 3. Desomer A, Heede, K. van der, Triemstra, M., Paget, J., Boer, D. de, Kohn, L.,  
8 Cleemput, I. Use of patient-reported outcome and experience measures in patient care  
9 and policy. Brussels: Belgian Health Care Knowledge, 2018.
- 10  
11  
12  
13 4. Foster A, Croot L, Brazier J, Harris J, O'Cathain A. The facilitators and barriers to  
14 implementing patient reported outcome measures in organisations delivering health  
15 related services: a systematic review of reviews. *J Patient Rep Outcomes*. 2018;2:46.
- 16  
17  
18  
19 5. Porter I, Goncalves-Bradley D, Ricci-Cabello I, Gibbons C, Gangannagaripalli J,  
20 Fitzpatrick R, et al. Framework and guidance for implementing patient-reported outcomes  
21 in clinical practice: evidence, challenges and opportunities. *J Comp Eff Res*. 2016;5(5):507-  
22 19.
- 23  
24  
25  
26  
27 6. Boudewijns EA, Claessens D, van Schayck OCP, Keijsers L, Salome PL, In 't Veen J,  
28 et al. ABC-tool reinvented: development of a disease-specific 'Assessment of Burden of  
29 Chronic Conditions (ABCC)-tool' for multiple chronic conditions. *BMC Fam Pract*.  
30 2020;21(1):11.
- 31  
32  
33  
34  
35 7. Keijsers LCEM, van Schayck OCP, Muris JWM, Boudewijns EA, Claessens D,  
36 Willemsen RTA, et al. Development and psychometric properties of the 'Assessment of  
37 Burden of Chronic Conditions (ABCC-)tool' for people with chronic heart failure (CHF).  
38 Manuscript Submitted. 2022.
- 39  
40  
41  
42  
43 8. Claessens D, Boudewijns EA, Keijsers LCEM, Gidding-Slok AHM, Winkens B, van  
44 Schayck OCP. Hitting the bullseye: the psychometric properties of the Assessment of  
45 Burden of Chronic Conditions (ABCC)-scale in the Netherlands. Manuscript Submitted.  
46 2022.
- 47  
48  
49  
50  
51 9. Boudewijns EA, Claessens D, Joore M, Keijsers L, van Schayck OCP, Winkens B, et  
52 al. Effectiveness and cost-effectiveness of the Assessment of Burden of Chronic Conditions  
53 (ABCC) tool in patients with COPD, asthma, diabetes mellitus type 2 and heart failure:  
54 protocol for a pragmatic clustered quasi-experimental study. *BMJ Open*.  
55 2020;10(11):e037693.
- 56  
57  
58  
59  
60

10. Stover AM, Haverman L, van Oers HA, Greenhalgh J, Potter CM, Group IPPiCPISW. Using an implementation science approach to implement and evaluate patient-reported outcome measures (PROM) initiatives in routine care settings. *Qual Life Res.* 2020.
11. Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci.* 2015;10:53.
12. Nilsen P, Bernhardsson S. Context matters in implementation science: a scoping review of determinant frameworks that describe contextual determinants for implementation outcomes. *BMC Health Serv Res.* 2019;19(1):189.
13. Gupta DM, Boland RJ, Jr., Aron DC. The physician's experience of changing clinical practice: a struggle to unlearn. *Implement Sci.* 2017;12(1):28.
14. Carroll C, Patterson M, Wood S, Booth A, Rick J, Balain S. A conceptual framework for implementation fidelity. *Implement Sci.* 2007;2:40.
15. Pinnock H, Barwick M, Carpenter CR, Eldridge S, Grandes G, Griffiths CJ, et al. Standards for Reporting Implementation Studies (StaRI): explanation and elaboration document. *BMJ Open.* 2017;7(4):e013318.
16. Pinnock H, Barwick M, Carpenter CR, Eldridge S, Grandes G, Griffiths CJ, et al. Standards for Reporting Implementation Studies (StaRI) Statement. *BMJ.* 2017;356:i6795.
17. Meier CA, Fitzgerald MC, Smith JM. eHealth: extending, enhancing, and evolving health care. *Annu Rev Biomed Eng.* 2013;15:359-82.
18. Kroneman M, Boerma W, van den Berg M, Groenewegen P, de Jong J, van Ginneken E. Netherlands: Health System Review. *Health Syst Transit.* 2016;18(2):1-240.
19. Huisman-de Waal G vAT, Schoonhoven L, et al. The Netherlands. In: Rafferty AM, Busse R, Zander-Jentsch B, et al., editors. *Strengthening health systems through nursing: Evidence from 14 European countries [Internet].* Copenhagen (Denmark): European Observatory on Health Systems and Policies; 2019. (Health Policy Series, No. 52.) 8. .
20. Rutten GEHM DGW, Nijpels G, Houweling B, Van de Laar F et al. NHG-Standaard 'Diabetes mellitus type 2' (derde herziening). *Huisarts Wet* 2013; 56: 512-525.

- 1  
2  
3 21. Smeele I BM, Broekhuizen B, Chavannes N, Veen J (2015). "NHG Standaard Astma  
4 bij volwassenen (derde herziening).  
5  
6
- 7 22. Snoeck-Stroband JB ST, Van Schayck CP, Muris JW, Van der Molen T et al. The  
8 Dutch College of General Practitioners (NHG) guidelines COPD, third revision. *Huisarts. Wet*  
9 2015. 58, 198–211.  
10
- 11 23. Hoes AW VA, Rutten FH, Van Lieshout J, Janssen PGH, Walma EP. The Dutch College  
12 of General Practitioners (NHG) guidelines heart failure, second revision, *Huisarts Wet*  
13 2010;53(7):368-89.  
14
- 15 24. Tsiachristas A, Dijkers C, Boland MR, Rutten-van Molken MP. Exploring payment  
16 schemes used to promote integrated chronic care in Europe. *Health Policy.*  
17 2013;113(3):296-304.  
18
- 19 25. Stetler CB, Legro MW, Wallace CM, Bowman C, Guihan M, Hagedorn H, et al. The  
20 role of formative evaluation in implementation research and the QUERI experience. *J Gen*  
21 *Intern Med.* 2006;21 Suppl 2:S1-8.  
22
- 23 26. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering  
24 implementation of health services research findings into practice: a consolidated  
25 framework for advancing implementation science. *Implement Sci.* 2009;4:50.  
26
- 27 27. Hennink M, Kaiser BN. Sample sizes for saturation in qualitative research: A  
28 systematic review of empirical tests. *Soc Sci Med.* 2022;292:114523.  
29
- 30 28. Vasileiou K, Barnett J, Thorpe S, Young T. Characterising and justifying sample size  
31 sufficiency in interview-based studies: systematic analysis of qualitative health research  
32 over a 15-year period. *BMC Med Res Methodol.* 2018;18(1):148.  
33
- 34 29. Slok AH, Twellaar M, Jutbo L, Kotz D, Chavannes NH, Holverda S, et al. 'To use or  
35 not to use': a qualitative study to evaluate experiences of healthcare providers and patients  
36 with the assessment of burden of COPD (ABC) tool. *NPJ Prim Care Respir Med.*  
37 2016;26:16074.  
38
- 39 30. Slok AH, Bemelmans TC, Kotz D, van der Molen T, Kerstjens HA, In 't Veen JC, et  
40 al. The Assessment of Burden of COPD (ABC) Scale: A Reliable and Valid Questionnaire.  
41 *COPD.* 2016;13(4):431-8.  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

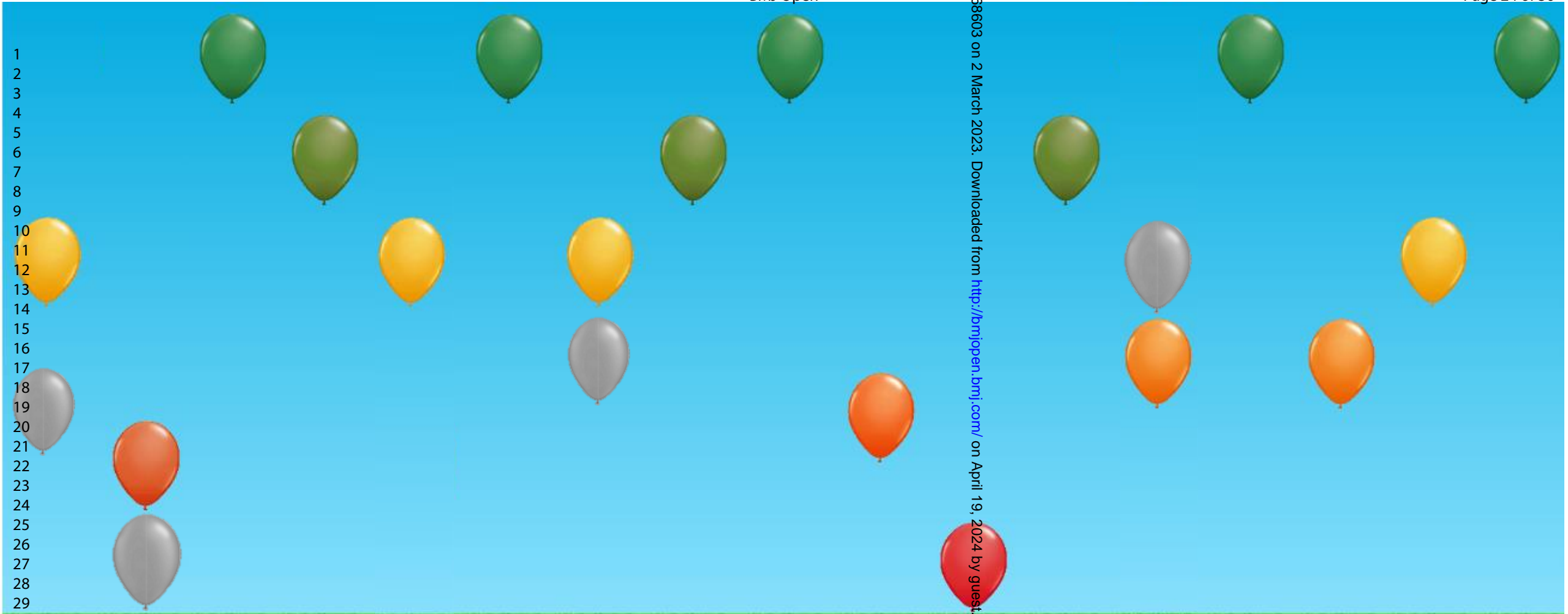
- 1  
2  
3 31. Slok AH, in 't Veen JC, Chavannes NH, van der Molen T, Rutten-van Molken MP,  
4 Kerstjens HA, et al. Development of the Assessment of Burden of COPD tool: an integrated  
5 tool to measure the burden of COPD. *NPJ Prim Care Respir Med*. 2014;24:14021.  
6  
7  
8
- 9 32. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health  
10 promotion interventions: the RE-AIM framework. *Am J Public Health*. 1999;89(9):1322-7.  
11  
12
- 13 33. Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, et al. RE-AIM  
14 Planning and Evaluation Framework: Adapting to New Science and Practice With a 20-Year  
15 Review. *Front Public Health*. 2019;7:64.  
16  
17
- 18 34. Forman J, Heisler M, Damschroder LJ, Kaselitz E, Kerr EA. Development and  
19 application of the RE-AIM QuEST mixed methods framework for program evaluation. *Prev*  
20 *Med Rep*. 2017;6:322-8.  
21  
22
- 23 35. Hasson H. Systematic evaluation of implementation fidelity of complex interventions  
24 in health and social care. *Implement Sci*. 2010;5:67.  
25  
26
- 27 36. Sundler AJ, Lindberg E, Nilsson C, Palmer L. Qualitative thematic analysis based on  
28 descriptive phenomenology. *Nurs Open*. 2019;6(3):733-9.  
29  
30
- 31 37. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation  
32 hybrid designs: combining elements of clinical effectiveness and implementation research  
33 to enhance public health impact. *Med Care*. 2012;50(3):217-26.  
34  
35
- 36 38. Kirchner JE, Smith JL, Powell BJ, Waltz TJ, Proctor EK. Getting a clinical innovation  
37 into practice: An introduction to implementation strategies. *Psychiatry Res*.  
38 2020;283:112467.  
39  
40
- 41 39. Waltz TJ, Powell BJ, Fernandez ME, Abadie B, Damschroder LJ. Choosing  
42 implementation strategies to address contextual barriers: diversity in recommendations  
43 and future directions. *Implement Sci*. 2019;14(1):42.  
44  
45
- 46 40. Bodenheimer T, Handley MA. Goal-setting for behavior change in primary care: an  
47 exploration and status report. *Patient Educ Couns*. 2009;76(2):174-80.  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60



1  
2  
3 **Figure 1: ABCC-tool visualization.** An example of the visualization of the outcomes of the  
4 ABCC-tool, in this case for someone with COPD and T2DM. Each balloon represents a unique  
5 domain in the ABCC-tool. Green balloons indicate low burden, yellow balloons indicate  
6 moderate burden, and red balloons indicate high burden. Grey balloons indicate the score from  
7 the previous visit for comparison. A separate “questions” open field shows the additional topics  
8 or questions that the patient proposed in the questionnaire.  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18

19 **Figure 2: Process of using ABCC-tool.** An overview of the cycle of using the ABCC-tool.  
20 The cycle starts at the assessing step, and then continues through the visualizing,  
21 communicating, and personalizing steps. After the initial evaluation, the visualizing step also  
22 facilitates the monitoring step because the balloons from the previous visit are presented in grey  
23 shades.  
24  
25  
26  
27  
28  
29  
30  
31  
32

33 **Figure 3: Overview of study design.** An overview of planned interview moments, specified  
34 by the goals of the interview and used frameworks. T0 is the baseline interview prior to actual  
35 use, with T1 and T2 following after 3 and 12 months of use respectively.  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60



32 Lung complaints    Lung attacks    Eating and drinking    Hypo    Worry about blood glucose    Leg and feet (DM)    Physical limitations    Fatigue    Night's rest    Feelings/emotions    Sexuality    Relations and work    Medicines    Weight (BMI)    Physical activity    Alcohol    Smoking

36 Questions:

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41

**Assessing**  
*ABCC-scale*

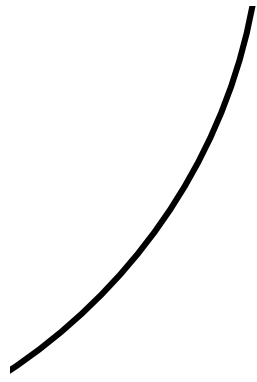
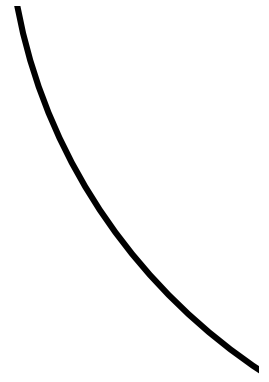
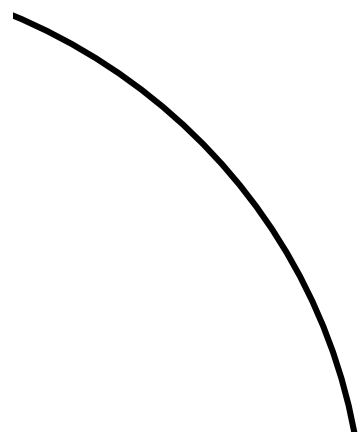
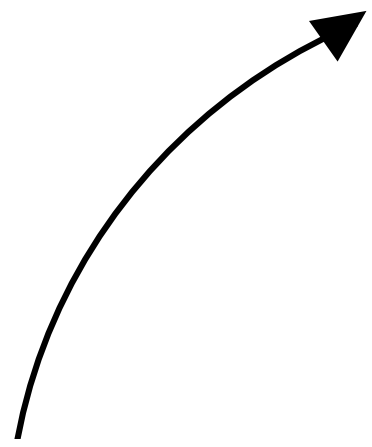
**Personalizing**  
*Goals and individual care plan*

**Visualizing**  
*Balloon diagram*

**Monitoring**  
*Self-management*

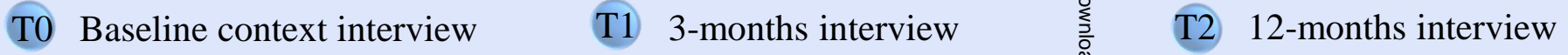
**Communicating**  
*Shared decision making*

22-068603 on 2 March 2023. Downloaded from <http://bmjopen.bmj.com/> on April 19, 2024 by guest. Protected by copyright.

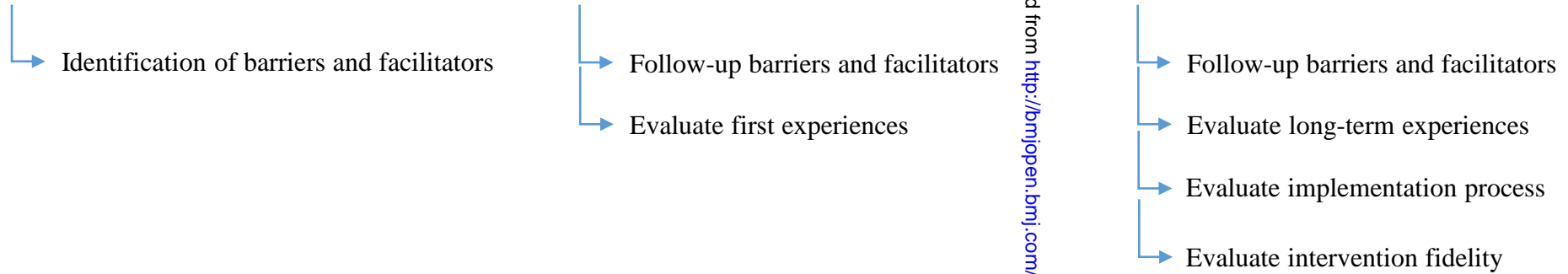


22-068603 on 2 March 2023. Downloaded from <http://bmjopen.bmj.com/> on April 19, 2024 by guest. Protected by copyright.

Timeline



Goals



Frameworks



1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41



## 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 CJ, 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;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 standards refers 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.
<b>Title and abstract</b>				
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.
<b>Introduction</b>				
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	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.		
<b>Methods: description</b>					
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		
<b>Methods: evaluation</b>					
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		

For peer review only

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

<b>Results</b>					
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		
<b>Discussion</b>					
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)
<b>General</b>					
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
<b>Intervention characteristics</b>			
Intervention source	Stakeholder's perception about development of the 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.
<b>Outer setting</b>			
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	-
<b>Inner setting</b>			
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	-
<b>Implementation climate</b>	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	-

1 2 3 4 5 6 7 8 9 10 11	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	-
12 13 14 15 16 17	<b>Readiness for implementation</b>	An umbrella-construct reflecting the organization's commitment to implementing the intervention. Sub-constructs of Readiness for Implementation (RI) are marked below	Yes	-
18 19 20 21	Leadership engagement (RI)	Stakeholder's perception of the commitment, involvement and accountability of leaders and managers in the organization	Yes	-
22 23 24 25 26	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	-
27 28 29 30 31 32 33 34 35 36 37 38 39 40	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.
41	<b>Individual characteristics</b>			
42 43 44 45 46 47	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	
48 49 50	Self-efficacy	The stakeholder's individual belief in their own capabilities to execute the implementation of the intervention	Yes	
51 52 53 54 55 56 57	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.
58 59 60	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	
<b>Process</b>			
Planning	The degree to which a scheme or method for implementation is designed in advance, and the quality of these schemes	No	<p>All process-constructs are left out of the interview for several reasons:</p> <ol style="list-style-type: none"> <li>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</li> <li>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)</li> </ol>
<b>Engaging</b>	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](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
<b>RE-AIM framework*</b>	
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). <i>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.</i>
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. <i>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.</i>
Implementation (see fidelity)	The fidelity (adherence) to the key components of the intervention, including deviations and adaptations made and the underlying reasons. <i>This construct is evaluated in more detail using the fidelity framework described below.</i>
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.
<b>Fidelity framework</b>	
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).
<b>Constructs that did not originate from theoretical frameworks</b>	
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).

# 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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-068603.R1
Article Type:	Protocol
Date Submitted by the Author:	06-Feb-2023
Complete List of Authors:	<p>Claessens, Danny; Maastricht University, Department of Family Medicine  Vervloet, Marcia; Netherlands Institute for Health Services Research  Boudewijns, Esther Adriana; Maastricht University Faculty of Health  Medicine and Life Sciences  Keijsers, Lotte C.E.M. ; Maastricht University Faculty of Health Medicine  and Life Sciences  Gidding-Slok, Annerika; Maastricht University, CAPHRI School for Public  Health and Primary care, Department of Family Medicine  van Schayck, Onno; Maastricht University, HAG  van Dijk, Liset; NIVEL Netherlands institute for health services research</p>
<b>Primary Subject Heading</b>:	General practice / Family practice
Secondary Subject Heading:	Diabetes and endocrinology, Qualitative research, Research methods, Respiratory medicine
Keywords:	PRIMARY CARE, DIABETES & ENDOCRINOLOGY, Change management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Asthma < THORACIC MEDICINE, Chronic airways disease < THORACIC MEDICINE

SCHOLARONE™  
Manuscripts

1  
2  
3 1 **Understanding the healthcare providers' perspective for bringing the Assessment of**  
4  
5 2 **Burden of Chronic Conditions tool to practice: a protocol for an implementation study**  
6  
7  
8 3

9  
10 4 Danny Claessens<sup>1</sup>, Marcia Vervloet<sup>2</sup>, Esther A. Boudewijns<sup>1</sup>, Lotte C.E.M. Keijsers<sup>1</sup>, Annerika  
11  
12 5 H.M. Gidding-Slok<sup>1</sup>, Onno C.P. van Schayck<sup>1</sup>, Liset van Dijk<sup>2,3</sup>  
13  
14 6

15  
16  
17 7 <sup>1</sup> Department of Family Medicine, Care and Public Health Research Institute (CAPHRI),  
18  
19 8 Maastricht University, Maastricht, the Netherlands

20  
21 9 <sup>2</sup> Nivel, Netherlands Institute for Health Services Research, Utrecht, the Netherlands

22  
23  
24 10 <sup>3</sup> Department of Pharmacotherapy, -Epidemiology and -Economics, Groningen Research  
25  
26 11 Institute of Pharmacy, Faculty of Science and Engineering, University of Groningen,  
27  
28 12 Groningen, the Netherlands  
29  
30

31 13  
32  
33 14 Corresponding author: Danny Claessens

34  
35 15 P.O. Box 616, 6200 MD Maastricht, the Netherlands

36  
37 16 Phone: +3143-3882836

38  
39  
40 17 [danny.claessens@maastrichtuniversity.nl](mailto:danny.claessens@maastrichtuniversity.nl)  
41

42 18

43 19 Word count: 3771  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60



## 20 **Abstract**

### 21 *Introduction*

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

### 29 *Methods and analysis*

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

### 42 *Ethics and dissemination*

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

1  
2  
3 45 the study. The results from the study in this protocol will be disseminated through publication  
4  
5 46 in peer-reviewed scientific journals and conference presentations.  
6  
7  
8 47

9  
10 48 **Key words:** Assessment of Burden of Chronic Conditions (ABCC-) tool, burden of disease,  
11  
12 49 patient-centered care, implementation, context, Consolidated Framework for Implementation  
13  
14 50 Research (CFIR), process, RE-AIM, fidelity framework, general practice, primary care  
15  
16

17 51

### 18 19 52 **Strengths and limitations of this study**

- 20  
21 53
- 22 • Implementation-effectiveness hybrid studies enable the combination of quantitative and  
23 qualitative outcomes, and therefore a better understanding of the complex reality of  
24 54 implementing novel interventions. These studies, however, are rarely conducted in  
25 55 primary care.  
26  
27  
28 56
  - 29 • Studying the determinants of implementation, implementation fidelity and  
30 57 implementation outcomes alongside an effectiveness trial bridges the gap between  
31 58 research and practice.  
32  
33  
34 59
  - 35 • The temporal design of this study enables to understand the development of identified  
36 60 barriers and facilitators to implementation over time.  
37  
38 61
  - 39 • A limitation of this study is that the its design alongside an effectiveness trial does not  
40 62 allow for the deployment or alteration of implementation strategies during the  
41 63 effectiveness study.  
42  
43  
44 64
  - 45 • Patients' experiences are not studied in this presented study, but will be evaluated in a  
46 65 separate study.  
47  
48  
49 66  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## 67 **Introduction**

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

90

1  
2  
3 91 Implementation is a broad term describing all efforts that are made to bring an intervention,  
4  
5 92 such as the ABCC-tool, to actual use in daily practice. These efforts are roughly divided in  
6  
7 93 efforts that either: 1) guide translation to clinical practice, 2) understand determinants of  
8  
9 94 implementation, and/or 3) evaluate the actual implementation (11). With respect to the ABCC-  
10  
11 95 tool, barriers and facilitators to actual use are determinants of implementation and can be  
12  
13 96 identified in the context of the end user (12). Experiences with using the tool may either  
14  
15 97 stimulate or hinder its use as it changes daily practice (13). It is also important to understand  
16  
17 98 how the tool is actually being used, as this may not be identical to how it is intended (i.e.  
18  
19 99 fidelity) (14). Knowing the determinants and the process of implementation enables the  
20  
21  
22  
23 100 development of tailored implementation strategies that support clinicians in integrating the tool  
24  
25 101 as part of routine care. In case of the ABCC-tool, the determinants of the implementation  
26  
27 102 process, such as how HCPs' context and fidelity to the intervention influence the experiences  
28  
29 103 of working with the ABCC-tool, are not yet known.  
30  
31  
32

33 104  
34  
35 105 In order to understand the implementation of the ABCC-tool in general practices, the underlying  
36  
37 106 determinants and process to implementation need to be understood. When these are understood,  
38  
39 107 they can be used for improvements to the ABCC-tool, as well as the development of tailored  
40  
41 108 implementation strategies, to facilitate implementation at a larger scale. The aim of this paper  
42  
43 109 is therefore to describe a study protocol for the assessment of 1) the barriers and facilitators for  
44  
45 110 HCPs to implement the ABCC-tool, and 2) implementation outcomes concerning the ABCC-  
46  
47 111 tool in general practices in the Netherlands.  
48  
49  
50

51 112

### 52 113 **Methods and analysis**

53  
54 114 The Standards for Reporting Implementation Studies (StaRI) were considered while composing  
55  
56 115 this study protocol (see appendix 1) (15, 16). This implementation study will be conducted  
57  
58  
59  
60

1  
2  
3 116 alongside an effectiveness trial (details of the effectiveness-part of the study are described  
4  
5 117 elsewhere (9)). In short, a pragmatic clustered quasi-experimental study will be conducted in  
6  
7 118 general practices in the Netherlands evaluating the effect of the ABCC-tool on patients'  
8  
9  
10 119 perceived quality of care, quality of life, patient activation, capability well-being and costs.  
11  
12 120 Patients from 18 intervention practices and 18 control practices will be followed for 18 months.  
13  
14 121 HCPs will act as interventionists using the ABCC-tool in the effectiveness trial while being the  
15  
16  
17 122 participants in the implementation study.  
18

19 123

### 21 124 The ABCC-tool

23  
24 125 The ABCC-tool is developed to guide the conversation between a HCP and a patient towards a  
25  
26 126 personalized care plan, by integrating experienced burden in the conversation (6). The cycle of  
27  
28 127 using the ABCC-tool contains several steps (figure 2). First, the patient completes a  
29  
30 128 questionnaire regarding their experienced burden (i.e. with different scales for people with  
31  
32 129 asthma, COPD, T2DM or CHF). Second, the outcomes of the questionnaire are digitally  
33  
34 130 transformed into a balloon chart visualization (figure 1) (6). Third, both the HCP and patient  
35  
36 131 discuss the presented balloons and pick one or more balloons of the patients choosing to  
37  
38 132 elaborate on during that particular consultation. Upon clicking on one of the balloons,  
39  
40 133 guideline-based treatment advice is presented as an in-screen pop-up. The fourth step in the  
41  
42 134 cycle is to formulate a specific care goal and plan, fueled by the treatment advice and the  
43  
44 135 possibilities and chances in the patient's context. Fifth, during the next consultation, the  
45  
46 136 balloons that were visualized in the previous consultation are presented in grey while displaying  
47  
48 137 the current balloons in color (see figure 1). Displaying the differences in this way allows for  
49  
50 138 easy monitoring of the progress of experienced burden by the HCP and patient. . Aside from  
51  
52 139 the practical components of the ABCC-tool, several other core components are key to its  
53  
54 140 application but are of adaptable nature. In order to facilitate quick application, HCPs are  
55  
56  
57  
58  
59  
60

1  
2  
3 141 instructed to have patients prepare the questionnaire at home or in the waiting room, prior to  
4  
5 142 the actual consultation. HCPs are further instructed to facilitate an active patient participation  
6  
7 143 in the choosing and discussing of relevant domains (balloons), applying the principles of  
8  
9 144 shared-decision making (17). Another key component of the ABCC-tool is to formulate  
10  
11 145 concrete and clear care goals and plans using the SMARTi-principles (18), and to monitor a  
12  
13 146 patient's progress during the beginning of the next consultation. The ABCC-tool will be used  
14  
15 147 during each routine consultation as described above.  
16  
17  
18

19 148

### 20 21 149 Population and recruitment

22  
23 150 The target population in this study comprises HCPs in primary care, which will be recruited  
24  
25 151 from the intervention arm of the effectiveness trial. All HCPs work in general practices in the  
26  
27 152 Netherlands as general practitioner (GP), practice nurse, or nurse practitioner. For this study,  
28  
29 153 HCPs are only eligible if they provided care for people with COPD, asthma, T2DM or CHF.  
30  
31 154 These HCPs use either a specific General Practice Information System (i.e. MicroHIS) or an  
32  
33 155 Integrated Care Information System (i.e. MediX) in which the ABCC-tool was technically  
34  
35 156 integrated. Coding and analyses will be performed separately for two subgroups of participants  
36  
37 157 based on whether they used either MicroHIS or MediX to use the ABCC-tool. The reason for  
38  
39 158 this is that differences between these information systems exist in their users' context, access  
40  
41 159 to the ABCC-tool (e.g. both HCP and patient can access the tool), and use of the ABCC-tool  
42  
43 160 (e.g. patients complete the questionnaire digitally). Particularly, HCPs that use MediX are  
44  
45 161 grouped in the same care group named ZIO (see box 1), while MicroHIS users are HCPs from  
46  
47 162 various care groups. Studying these groups separately allows for the study of implementation  
48  
49 163 in two distinct real-world contexts. A detailed description of these differences is provided in  
50  
51 164 table 1. Because participating HCPs are interviewed during office hours, a total of three hours  
52  
53 165 at an average practice nurse salary rate will be compensated to the practice in which they work.  
54  
55  
56  
57  
58  
59  
60

167 **Table 1: Description of distinctive subgroups.**

	<b>MediX-users</b>	<b>MicroHIS-users</b>
<b>Context</b>		
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
<b>Access to ABCC-tool</b>		
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
<b>Using ABCC-tool</b>		
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	

168 *An overview of the differences between the two subgroups of HCPs in this study. Abbreviations:*

169 *ABCC = Assessment of Burden of Chronic Conditions; ZIO = Zorg in Ontwikkeling (Dutch),*

170 *which is the name of the participating care group*

171

### 172 Context of care

173 In the Netherlands, provision of healthcare is layered based on its financial structure (19).

174 Primary care in the Netherlands is provided by general practitioners at general practices, who

175 act as a gatekeeper to secondary care (19). General practices in the Netherlands are either a

176 single GP practice, multiple GP practice, or GP practice imbedded in a medical center (i.e.

1  
2  
3 177 single or multiple GP's collaborating with other primary care providers). General practitioners  
4  
5 178 provide, as the name implies, care to people with any condition. Practice nurses and nurse  
6  
7  
8 179 practitioners in the Netherlands provide care for people with chronic somatic conditions (e.g.  
9  
10 180 pulmonary disease, T2DM, cardiovascular disease, or a combination) or mental disease to a  
11  
12 181 varying degree of independence (i.e. practice nurses are supervised by general practitioners  
13  
14 182 whereas nurse practitioners are independent HCPs) (20). General practice-provided care in the  
15  
16  
17 183 Netherlands is strongly guided by the guidelines of the Dutch College of General Practitioners.  
18  
19 184 As part of these guidelines, people with chronic conditions regularly visit their HCP when their  
20  
21 185 condition is stable (i.e. once or twice a year for people with asthma or COPD, and four times a  
22  
23 186 year for people with T2DM or CHF), or more often if necessary (21-24).  
24  
25  
26 187

#### **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.

188

#### 189 Study design

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



1  
2  
3 195 description of the context will be used to identify barriers and facilitators to implementation.  
4  
5 196 After three months (T1), a follow-up interview will be held to reflect on the first experiences  
6  
7 197 with the ABCC-tool and the status of the identified barriers and facilitators from T0. If any  
8  
9 198 other barriers or facilitators arise in the three months of use, they will be added to the list of  
10  
11 199 barriers and facilitators that will be discussed during the next interview after 12 months. At T2,  
12  
13 200 also a process evaluation of experiences, uptake into routine practice, and fidelity of the ABCC-  
14  
15 201 tool will take place using the RE-AIM and fidelity frameworks. Participant will remain the  
16  
17 202 same throughout the study period (i.e. three consecutive interviews per participant). One  
18  
19 203 researcher (DC) will perform all interviews to maintain stability in the interaction between the  
20  
21 204 researcher and participant.  
22  
23  
24  
25  
26  
27

#### 28 206 Sample size

29  
30 207 Participants in this implementation study will be a subsample of the participating HCPs in the  
31  
32 208 effectiveness trial, and thus a convenience sample. Empirically, qualitative data saturation is  
33  
34 209 reached on average after 12-13 interviews (28). In a comparable qualitative evaluation of the  
35  
36 210 ABCC-tool's predecessor (the ABC-tool specific for COPD), 9 out of 15 participants were  
37  
38 211 sufficient to observe theoretical data saturation in a similarly homogeneous population.  
39  
40 212 Therefore, a maximum of 15 participants per group are estimated to observe theoretical data  
41  
42 213 saturation and to allow for transferability of the results (29, 30).  
43  
44  
45  
46  
47  
48

#### 49 215 Implementation strategy

50  
51 216 Several non-directed implementation strategies are deployed to facilitate clinicians to use the  
52  
53 217 tool. First, the ABCC-tool is implemented as an incorporated tool in the information systems  
54  
55 218 that HCPs use, and not in a separate environment. A stand-alone program was previously  
56  
57 219 identified a barrier to the implementation of the ABCC-tool's predecessor, the Assessment of  
58  
59  
60

1  
2  
3 220 Burden of COPD tool (30-32) (tailoring strategies from the Expert Recommendations for  
4  
5 221 Implementing Change (ERIC) (33, 34)). Prior experience of the HCP with this predecessor will  
6  
7  
8 222 be allowed for the HCP, but not for the patients who participate in the effectiveness trial.  
9  
10 223 Second, regardless of prior knowledge, all HCPs will receive a document and an overview  
11  
12 224 poster with information on how to use the ABCC-tool, and an explanation video presented by  
13  
14 225 the researchers which is accessible only with a specific weblink (i.e. development and  
15  
16 226 distribution of educational materials from ERIC (33, 34)). HCPs will not be physically or  
17  
18 227 digitally trained to use the ABCC-tool. However, they may have had training in the use of its  
19  
20 228 predecessor. Whether participants have had training and/or experience will be asked during the  
21  
22 229 first interview and will be included in the description of the context. Additional to the strategy  
23  
24 230 described above, HCPs that use the Integrated Care Information System have more support  
25  
26 231 during the trial because they are all part of the same care group. Researchers join in monthly  
27  
28 232 meetings with the care group and patient platform staff to evaluate and assist in the  
29  
30 233 implementation process (i.e. build a coalition from ERIC (33, 34)). This support is primarily  
31  
32 234 provided by staff from the care group and staff from the patient platform, and concerned help  
33  
34 235 in the recruitment of patients for the effectiveness trial and technical support (i.e. provide local  
35  
36 236 technical assistance from ERIC (33, 34)). This additional support by the care group and patient  
37  
38 237 platform was not possible for HCPs outside of the participating care group and justifies having  
39  
40 238 two subgroups of participants in the analyses (MicroHIS-users versus MediX-users). To  
41  
42 239 minimize the impact of the implementation study on the outcomes of the effectiveness study,  
43  
44 240 all identified improvements will be implemented after the trial period. Only problems that  
45  
46 241 would lead to the HCP not being able to use the ABCC-tool (i.e. technical errors) will be tackled  
47  
48 242 during the study period.  
49  
50  
51  
52  
53  
54  
55  
56  
57

58 244 Study outcomes  
59  
60

1  
2  
3 245 The outcomes of this study are divided as: 1) determinants of implementation (the barriers and  
4  
5 246 facilitators for HCPs to implement the ABCC-tool), 2) implementation outcomes.  
6  
7  
8 247

9  
10 248 Participant demographics will be collected regarding: practice size, type of practice (GP  
11  
12 249 practice or medical center), experience using the intervention's predecessor, age, sex, education  
13  
14 250 (higher education, vocational education as either nurse or doctor's assistant), function (general  
15  
16 251 practitioner, nurse practitioner or practice nurse), target population (COPD, asthma, diabetes  
17  
18 252 mellitus type 2, heart failure, or a combination), and an estimate of the target population's socio-  
19  
20 253 economic status (as viewed by the HCP).  
21  
22  
23  
24 254

25  
26 255 At the beginning of the study and as determinants of the implementation process, the barriers  
27  
28 256 and facilitators to implementing the ABCC-tool will be identified from the context of the  
29  
30 257 participating HCPs using the CFIR (27). CFIR is a determinant framework to assess the  
31  
32 258 presence of barriers or facilitators of study participants within their organization, and is often  
33  
34 259 used for studying the implementation of a PROM (or in this case a tool containing a PROM)  
35  
36 260 (4, 11). CFIR defines five domains (i.e. intervention characteristics, inner setting, outer setting,  
37  
38 261 individual characteristics, and process) containing 39 constructs that are known to influence  
39  
40 262 implementation (27). The CFIR constructs are used to compose an interview guide that targets  
41  
42 263 all constructs that are expected to be of influence on the implementation of the ABCC-tool in  
43  
44 264 general practices in the Netherlands. A selection of CFIR constructs is made in order to  
45  
46 265 minimize the time burden of the interview on HCPs to a maximum of 60 minutes while still  
47  
48 266 focusing on the constructs that seem most relevant a priori. A selection of relevant CFIR  
49  
50 267 constructs was made by three researchers (DC, MV, LD) over the course of multiple discussion  
51  
52 268 rounds and based on consensus. Trial design implications and the context of Dutch primary care  
53  
54 269 were taken into account when evaluating the informative value of each CFIR construct. An  
55  
56  
57  
58  
59  
60

1  
2  
3 270 overview of CFIR constructs and the choices whether or not to include them in the interview  
4  
5 271 guide are presented in appendix 2. Identified barriers and facilitators will be followed up on  
6  
7 272 during the two sequential interviews to evaluate how these barriers and facilitators are managed  
8  
9 273 during the study period. HCPs will also be asked for any additional barriers and facilitators that  
10  
11 274 are experienced after the first interview.  
12  
13  
14  
15 275

16  
17 276 Implementation outcomes will be qualitatively evaluated using the Reach-Effectiveness-  
18  
19 277 Adoption-Implementation-Maintenance (RE-AIM) framework (35-37). Reach will only be  
20  
21 278 limitedly assessed because HCPs are instructed to recruit 10 eligible patients to participate in  
22  
23 279 the study, and as such Reach is predetermined. The Effectiveness of the ABCC-tool will be  
24  
25 280 evaluated as whether HCPs notice any influence of the ABCC-tool on patients, specifically in  
26  
27 281 terms of quality of care, quality of life, or the level of active involvement in the care process.  
28  
29 282 Objective effectiveness will not be evaluated as this is part of the effectiveness study. Adoption  
30  
31 283 will be evaluated as the extent to which HCPs integrated the ABCC-tool into the consultations  
32  
33 284 with the participating patients. This also includes whether the tool is being used by the GP,  
34  
35 285 nurse practitioner and/or practice nurse. The Implementation domain of the RE-AIM  
36  
37 286 framework constitutes fidelity, and will be evaluated in more depth using a fidelity framework  
38  
39 287 (described below). Maintenance will be evaluated as how HCPs are expecting to continue  
40  
41 288 working with the ABCC-tool, how they see the future of the ABCC-tool in their practice, and  
42  
43 289 whether steps are taken to actually maintain the use of the ABCC-tool.  
44  
45  
46  
47  
48

49 290  
50  
51 291 Implementation fidelity refers to the adherence to the intervention as it is intended and will be  
52  
53 292 evaluated using the framework for implementation fidelity by Carroll et. al. (14, 38). In this  
54  
55 293 framework, fidelity is characterized as adherence to the intervention at four levels: content,  
56  
57 294 coverage, frequency and duration. In order to adequately evaluate adherence to content, the  
58  
59  
60

1  
2  
3 295 ABCC-tool is described for all steps in the cycle of its use (figure 2). Evaluation of adherence  
4  
5 296 to the ABCC-tool content will focus on how HCPs have used each separate step in this cycle,  
6  
7 297 and whether this is performed as intended. The coverage of using the ABCC-tool will be  
8  
9  
10 298 evaluated as whether the tool was used in all participating patients. The frequency of use will  
11  
12 299 be evaluated by whether the ABCC-tool is used in each regular visit of the patient, for at least  
13  
14 300 12 months. The in-consult duration of using the ABCC-tool is intended to be within the regular  
15  
16 301 time for a consultation by a nurse practitioner, which is 20-30 minutes in the Netherlands. The  
17  
18 302 time spent on the ABCC-tool will be evaluated qualitatively in order to assess whether this fell  
19  
20 303 within this time frame and/or whether this was acceptable to the HCP. In the case that the use  
21  
22 304 of the ABCC-tool is not as intended, reasons for this deviation will be explored. An interview  
23  
24 305 topic guide of the process evaluation is presented in appendix 3.  
25  
26  
27  
28  
29

306

### 307 Data analyses

308 All interviews will be audio-recorded, transcribed verbatim at literatim and anonymized. All  
309 interviews will be independently coded by two researchers. Analyses are described per  
310 interview moment, and for each outcome separately.  
311

312

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

319

1  
2  
3 320 The T1 interview will be completely processed using inductive coding. As no theoretical  
4  
5 321 framework is used for the T1 interview, a thematic analysis of the T1 interview will identify  
6  
7 322 the themes that represent the lived experience of HCPs after three months of practice by means  
8  
9 323 of phenomenology (39).

10  
11  
12 324  
13  
14 325 The T2 interview will be processed using deductive coding according to the domains that are  
15  
16 326 formulated by the RE-AIM and fidelity frameworks. The data will be analyzed by one  
17  
18 327 researcher (DC) and discussed with another researcher (MV), upon disagreement a third  
19  
20 328 researcher (LD) will decide. All data will be analyzed from a constructivist/interpretivist  
21  
22 329 research paradigm, where understanding the subjective experience of HCPs is the main focus.  
23  
24 330 As the T2 interview mainly includes personal experiences, a thematic analysis of the T2  
25  
26 331 interview will be performed to identify relevant themes within the boundaries of both  
27  
28 332 frameworks (i.e. the interviews at T2 contain questions on the two frameworks, an overview of  
29  
30 333 which is presented in appendix 3). By means of phenomenology, the experiences of using and  
31  
32 334 implementing the ABCC-tool will be evaluated.  
33  
34  
35  
36  
37  
38  
39

#### 40 336 Patient and public involvement statement

41  
42 337 Patients, patient advocacy groups, and as healthcare providers (HCPs) were involved as an  
43  
44 338 expert group during the development of the Assessment of Burden of Chronic Conditions  
45  
46 339 (ABCC-)tool, the main intervention in this study protocol. HCPs or patients were not directly  
47  
48 340 involved in the design or conduct of this protocol.  
49  
50

51 341  
52  
53 342 **Discussion**  
54  
55 343 The ABCC-tool is developed by, with, and for HCPs and people with chronic conditions (i.e.  
56  
57 344 COPD, asthma, T2DM, and CHF). Understanding their perspective and experiences enables us  
58  
59  
60

1  
2  
3 345 to fully adapt the tool to meet their requirements and needs in clinical practice. The other way  
4  
5 346 around, understanding how the ABCC-tool is used and implemented in a specific context,  
6  
7 347 enables us to facilitate implementation in other settings. Understanding the extent to which  
8  
9 348 HCPs have implemented the ABCC-tool into the consultation with patients, and which barriers  
10  
11 349 and facilitators hinder or stimulate this, helps to identify how HCPs can optimally be supported  
12  
13 350 in the implementation process. Lastly, knowing how the ABCC-tool is used and the reasons for  
14  
15 351 deviations from the intended use, helps us to understand whether the ABCC-tool requires  
16  
17 352 adjustments to local settings or whether specific training is necessary.  
18  
19  
20  
21  
22 353

23  
24 354 This study protocol describes an implementation study alongside an effectiveness trial. The  
25  
26 355 major strength of the study lays in the hybrid nature of measuring effects in patients (i.e.  
27  
28 356 recipients of the intervention) as well as studying the application and context of HCPs (i.e.  
29  
30 357 providers of the intervention) (40). Another strength of this study design is the follow-up on  
31  
32 358 contextual factors to the implementation of the ABCC-tool. This temporal design enables us to  
33  
34 359 understand the development of barriers and facilitators over an extended period of use of the  
35  
36 360 ABCC-tool. Possibly, some barriers may be solved by the passing of time (i.e. through  
37  
38 361 experience or changing conditions) and new ones may arise. Alternatively, facilitators may also  
39  
40 362 appear only as a temporary factor (i.e. only facilitating at the start). The use of the well-studied  
41  
42 363 frameworks of CFIR, RE-AIM and the Fidelity framework from Carroll et al. strengthens the  
43  
44 364 observations made during this study. The use of the CFIR additionally enables the selection of  
45  
46 365 potential implementation strategies to resolve the identified barriers and facilitators through the  
47  
48 366 Expert Recommendation for Implementing Change (ERIC-) tool (33, 34). These strategies are  
49  
50 367 mapped on CFIR constructs to facilitate choosing ideal implementation strategies, though a  
51  
52 368 best-fit strategy should always match the local context. Lastly, studying the implementation in  
53  
54 369 two contextually different groups enables us to empirically describe the similarities and  
55  
56  
57  
58  
59  
60

1  
2  
3 370 differences between the two groups. The fact that HCPs from one group have a different  
4  
5 371 organization of care and access to the intervention makes uniform conclusions rather difficult.  
6  
7  
8 372 However, implementation is always subject to local context and supports a case-by-case  
9  
10 373 approach. The results from this implementation study enable us to describe the relevant  
11  
12 374 contextual factors for the implementation of the ABCC-tool in two contextually different  
13  
14  
15 375 settings.

16  
17 376 A limitation of this study is that a selection of CFIR constructs is made. Possibly, relevant  
18  
19 377 contextual factors will be missed because of this. However, evaluating the full scope of CFIR  
20  
21 378 would be too time demanding. The selection was made with careful consideration of the trial  
22  
23  
24 379 design and the national context of primary care (see appendix 2) in several discussion rounds  
25  
26 380 by three researchers (DC, MV, LD). Involving HCPs in the design of this study could have  
27  
28 381 reduced the risk of selection bias even further. Furthermore, due to the design this research,  
29  
30 382 targeted implementation strategies cannot be deployed until after the study period. In order to  
31  
32 383 evaluate patient outcomes in the effectiveness trial, changes to the intervention or its  
33  
34 384 implementation were not allowed during the trial to minimize their impact on effectiveness  
35  
36 385 outcomes. While this approach delays supporting the implementation process, it does allow  
37  
38 386 barriers and facilitators to be followed and to develop implementation strategies to those  
39  
40 387 determinants that are actually in need of support. Additionally, this study does not weigh in the  
41  
42 388 experiences and context of participating patients in the effectiveness trial. In order to minimize  
43  
44 389 the influence of this implementation study on the effect that is measured in patients, an  
45  
46 390 evaluation of patient experiences is planned to take place after finalizing the data collection in  
47  
48 391 the effectiveness trial. This will enable us to study the experiences of patients after an extended  
49  
50 392 period of use while maintaining the integrity of current effectiveness measurements. The  
51  
52 393 effectiveness trial also imposed limitations on the eligible population and the use of the full  
53  
54 394 scope of the RE-AIM framework. With only a limited number of HCPs to include in this  
55  
56  
57  
58  
59  
60



1  
2  
3 395 implementation study, evaluating reach and organizational adoption will only be possible to  
4  
5 396 some extent.  
6  
7  
8 397

9  
10 398 Accounting for the above mentioned strengths and limitations, this study will enable to explore  
11  
12 399 the implementation of the ABCC-tool in a real world primary care setting. Studying the context  
13  
14 400 of HCPs strengthens our understanding of their starting perspective for implementing a novel  
15  
16 401 intervention such as this care-supporting tool. It also enables identification of (potential)  
17  
18 402 barriers and facilitators as well as to follow their development over time. Understanding the  
19  
20 403 local implementation process and difficulties facilitates the adaptation of the intervention and  
21  
22 404 the design of appropriate implementation strategies for broad implementation. As such this  
23  
24 405 study protocol is a first step towards the ABCC-tool's routine use in clinical practice in Dutch  
25  
26 406 primary care.  
27  
28  
29  
30  
31 407

## 32 33 408 **Ethics and dissemination**

### 34 35 409 *Ethics approval and consent*

36  
37 410 The presented study was approved by the Medical Ethics Committee of Zuyderland Hospital,  
38  
39 411 Heerlen (METCZ20180131). Written informed consent is mandatory prior to participation in  
40  
41 412 the study. Transcripts from the qualitative interviews will be deidentified for the privacy of the  
42  
43 413 participants.  
44  
45  
46  
47 414

### 48 49 415 *Dissemination*

50  
51 416 The results from the study in this protocol will be disseminated through publication in peer-  
52  
53 417 reviewed scientific journals and conference presentations. The results from this study will be  
54  
55 418 used to facilitate implementation in other practices through the development of tailored  
56  
57 419 implementation strategies.  
58  
59  
60

1  
2  
3 420  
4

5 421 **Declarations**

6  
7 422 *Competing interests*

8  
9  
10 423 The authors declare that they have no competing interests.  
11

12 424

13  
14 425 *Author's contributions*

15  
16 426 DC, MV and LD designed the study in close collaboration with EB, LK, AG and OS. DC wrote  
17  
18 427 the first version of the manuscript of this study protocol under supervision of MV and LD. All  
19  
20 428 authors have read and approved the final version of the manuscript.  
21  
22

23  
24 429

25  
26 430 *Funding*

27  
28 431 The work was supported by the Netherlands Organisation for Health Research and  
29  
30 432 Development, grant number 104006001. The funding organization had no influence on the  
31  
32 433 design or execution of the study nor writing the manuscript or the decision to publish.  
33  
34

35 434

36  
37 435 *Acknowledgements*

38  
39 436 We would like to express our gratitude to Leah Zullig, Hayden Bosworth and all colleagues at  
40  
41 437 the Duke Department of Population Health Sciences for their critical reflection on our study  
42  
43 438 design and allowing us to learn from their experience in the field of implementation sciences.  
44  
45

46 439

47  
48  
49 440 **References**

- 50  
51 441 1. Reuben DB, Sinsky CA. From Transactional Tasks to Personalized Care: A New Vision  
52  
53 442 of Physicians' Roles. *Ann Fam Med*. 2018;16(2):168-9.  
54  
55 443 2. Dawson J, Doll H, Fitzpatrick R, Jenkinson C, Carr AJ. The routine use of patient  
56  
57 444 reported outcome measures in healthcare settings. *BMJ*. 2010;340:c186.  
58  
59  
60

- 1  
2  
3 445 3. Desomer A, Heede, K. van der, Triemstra, M., Paget, J., Boer, D. de, Kohn, L.,  
4  
5 446 Cleemput, I. Use of patient-reported outcome and experience measures in patient care and  
6  
7 447 policy. Brussels: Belgian Health Care Knowledge, 2018.
- 8  
9  
10 448 4. Foster A, Croot L, Brazier J, Harris J, O'Cathain A. The facilitators and barriers to  
11  
12 449 implementing patient reported outcome measures in organisations delivering health related  
13  
14 450 services: a systematic review of reviews. *J Patient Rep Outcomes*. 2018;2:46.
- 15  
16  
17 451 5. Porter I, Goncalves-Bradley D, Ricci-Cabello I, Gibbons C, Gangannagaripalli J,  
18  
19 452 Fitzpatrick R, et al. Framework and guidance for implementing patient-reported outcomes in  
20  
21 453 clinical practice: evidence, challenges and opportunities. *J Comp Eff Res*. 2016;5(5):507-19.
- 22  
23  
24 454 6. Boudewijns EA, Claessens D, van Schayck OCP, Keijsers L, Salome PL, In 't Veen J,  
25  
26 455 et al. ABC-tool reinvented: development of a disease-specific 'Assessment of Burden of  
27  
28 456 Chronic Conditions (ABCC)-tool' for multiple chronic conditions. *BMC Fam Pract*.  
29  
30 457 2020;21(1):11.
- 31  
32  
33 458 7. Keijsers LCEM, van Schayck OCP, Muris JWM, Boudewijns EA, Claessens D,  
34  
35 459 Willemsen RTA, et al. Development and psychometric properties of the 'Assessment of Burden  
36  
37 460 of Chronic Conditions (ABCC)-tool' for people with chronic heart failure (CHF). Manuscript  
38  
39 461 Submitted. 2022.
- 40  
41  
42 462 8. Claessens D, Boudewijns EA, Keijsers LCEM, Gidding-Slok AHM, Winkens B, van  
43  
44 463 Schayck OCP. Validity and reliability of the Assessment of Burden of Chronic Conditions  
45  
46 464 (ABCC)-scale in the Netherlands. Manuscript accepted for publication in *Annals of Family*  
47  
48 465 *Medicine*. 2022.
- 49  
50  
51 466 9. Boudewijns EA, Claessens D, Joore M, Keijsers L, van Schayck OCP, Winkens B, et  
52  
53 467 al. Effectiveness and cost-effectiveness of the Assessment of Burden of Chronic Conditions  
54  
55 468 (ABCC) tool in patients with COPD, asthma, diabetes mellitus type 2 and heart failure: protocol  
56  
57 469 for a pragmatic clustered quasi-experimental study. *BMJ Open*. 2020;10(11):e037693.
- 58  
59  
60

- 1  
2  
3 470 10. Stover AM, Haverman L, van Oers HA, Greenhalgh J, Potter CM, Group IPPiCPISW.  
4  
5 471 Using an implementation science approach to implement and evaluate patient-reported outcome  
6  
7 472 measures (PROM) initiatives in routine care settings. *Qual Life Res.* 2020.
- 9  
10 473 11. Nilsen P. Making sense of implementation theories, models and frameworks. *Implement*  
11  
12 474 *Sci.* 2015;10:53.
- 14 475 12. Nilsen P, Bernhardsson S. Context matters in implementation science: a scoping review  
16  
17 476 of determinant frameworks that describe contextual determinants for implementation outcomes.  
18  
19 477 *BMC Health Serv Res.* 2019;19(1):189.
- 21 478 13. Gupta DM, Boland RJ, Jr., Aron DC. The physician's experience of changing clinical  
23  
24 479 practice: a struggle to unlearn. *Implement Sci.* 2017;12(1):28.
- 26 480 14. Carroll C, Patterson M, Wood S, Booth A, Rick J, Balain S. A conceptual framework  
27  
28 481 for implementation fidelity. *Implement Sci.* 2007;2:40.
- 30 482 15. Pinnock H, Barwick M, Carpenter CR, Eldridge S, Grandes G, Griffiths CJ, et al.  
32  
33 483 Standards for Reporting Implementation Studies (StaRI): explanation and elaboration  
34  
35 484 document. *BMJ Open.* 2017;7(4):e013318.
- 37 485 16. Pinnock H, Barwick M, Carpenter CR, Eldridge S, Grandes G, Griffiths CJ, et al.  
39  
40 486 Standards for Reporting Implementation Studies (StaRI) Statement. *BMJ.* 2017;356:i6795.
- 42 487 17. Elwyn G, Durand MA, Song J, Aarts J, Barr PJ, Berger Z, et al. A three-talk model for  
43  
44 488 shared decision making: multistage consultation process. *BMJ.* 2017;359:j4891.
- 46 489 18. Salter C, Shiner A, Lenaghan E, Murdoch J, Ford JA, Winterburn S, et al. Setting goals  
48  
49 490 with patients living with multimorbidity: qualitative analysis of general practice consultations.  
50  
51 491 *Br J Gen Pract.* 2019;69(684):e479-e88.
- 53 492 19. Kroneman M, Boerma W, van den Berg M, Groenewegen P, de Jong J, van Ginneken  
55  
56 493 E. Netherlands: Health System Review. *Health Syst Transit.* 2016;18(2):1-240.
- 57  
58  
59  
60

- 1  
2  
3 494 20. Huisman-de Waal G vAT, Schoonhoven L, et al. The Netherlands. In: Rafferty AM,  
4  
5 495 Busse R, Zander-Jentsch B, et al., editors. Strengthening health systems through nursing:  
6  
7 496 Evidence from 14 European countries [Internet]. Copenhagen (Denmark): European  
8  
9 497 Observatory on Health Systems and Policies; 2019. (Health Policy Series, No. 52.) 8. .
- 10  
11  
12 498 21. Rutten GEHM DGW, Nijpels G, Houweling B, Van de Laar F et al. The Dutch College  
13  
14 499 of General Practitioners (NHG) guidelines Diabetes mellitus type 2, third revision. Huisarts  
15  
16 500 Wet 2013; 56: 512-525.
- 17  
18  
19 501 22. Smeele I BM, Broekhuizen B, Chavannes N, Veen J (2015). The Dutch College of  
20  
21 502 General Practitioners (NHG) guidelines asthma in adults, third revision. Huisarts Wet  
22  
23 503 2015;58(3):142-54.
- 24  
25  
26 504 23. Snoeck-Stroband JB ST, Van Schayck CP, Muris JW, Van der Molen T et al. The Dutch  
27  
28 505 College of General Practitioners (NHG) guidelines COPD, third revision. Huisarts. Wet 2015.  
29  
30 506 58, 198–211.
- 31  
32  
33 507 24. Hoes AW VA, Rutten FH, Van Lieshout J, Janssen PGH, Walma EP. The Dutch College  
34  
35 508 of General Practitioners (NHG) guidelines heart failure, second revision, Huisarts Wet  
36  
37 509 2010;53(7):368-89.
- 38  
39  
40 510 25. Tsiachristas A, Dikkers C, Boland MR, Rutten-van Molken MP. Exploring payment  
41  
42 511 schemes used to promote integrated chronic care in Europe. Health Policy. 2013;113(3):296-  
43  
44 512 304.
- 45  
46  
47 513 26. Stetler CB, Legro MW, Wallace CM, Bowman C, Guihan M, Hagedorn H, et al. The  
48  
49 514 role of formative evaluation in implementation research and the QUERI experience. J Gen  
50  
51 515 Intern Med. 2006;21 Suppl 2:S1-8.
- 52  
53  
54 516 27. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering  
55  
56 517 implementation of health services research findings into practice: a consolidated framework for  
57  
58 518 advancing implementation science. Implement Sci. 2009;4:50.
- 59  
60

- 1  
2  
3 519 28. Hennink M, Kaiser BN. Sample sizes for saturation in qualitative research: A systematic  
4  
5 520 review of empirical tests. *Soc Sci Med.* 2022;292:114523.  
6  
7  
8 521 29. Vasileiou K, Barnett J, Thorpe S, Young T. Characterising and justifying sample size  
9  
10 522 sufficiency in interview-based studies: systematic analysis of qualitative health research over a  
11  
12 523 15-year period. *BMC Med Res Methodol.* 2018;18(1):148.  
13  
14  
15 524 30. Slok AH, Twellaar M, Jutbo L, Kotz D, Chavannes NH, Holverda S, et al. 'To use or  
16  
17 525 not to use': a qualitative study to evaluate experiences of healthcare providers and patients with  
18  
19 526 the assessment of burden of COPD (ABC) tool. *NPJ Prim Care Respir Med.* 2016;26:16074.  
20  
21  
22 527 31. Slok AH, Bemelmans TC, Kotz D, van der Molen T, Kerstjens HA, In 't Veen JC, et al.  
23  
24 528 The Assessment of Burden of COPD (ABC) Scale: A Reliable and Valid Questionnaire. *COPD.*  
25  
26 529 2016;13(4):431-8.  
27  
28  
29 530 32. Slok AH, in 't Veen JC, Chavannes NH, van der Molen T, Rutten-van Molken MP,  
30  
31 531 Kerstjens HA, et al. Development of the Assessment of Burden of COPD tool: an integrated  
32  
33 532 tool to measure the burden of COPD. *NPJ Prim Care Respir Med.* 2014;24:14021.  
34  
35  
36 533 33. Kirchner JE, Smith JL, Powell BJ, Waltz TJ, Proctor EK. Getting a clinical innovation  
37  
38 534 into practice: An introduction to implementation strategies. *Psychiatry Res.* 2020;283:112467.  
39  
40  
41 535 34. Waltz TJ, Powell BJ, Fernandez ME, Abadie B, Damschroder LJ. Choosing  
42  
43 536 implementation strategies to address contextual barriers: diversity in recommendations and  
44  
45 537 future directions. *Implement Sci.* 2019;14(1):42.  
46  
47  
48 538 35. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health  
49  
50 539 promotion interventions: the RE-AIM framework. *Am J Public Health.* 1999;89(9):1322-7.  
51  
52  
53 540 36. Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, et al. RE-AIM  
54  
55 541 Planning and Evaluation Framework: Adapting to New Science and Practice With a 20-Year  
56  
57 542 Review. *Front Public Health.* 2019;7:64.  
58  
59  
60

- 1  
2  
3 543 37. Forman J, Heisler M, Damschroder LJ, Kaselitz E, Kerr EA. Development and  
4  
5 544 application of the RE-AIM QuEST mixed methods framework for program evaluation. *Prev*  
6  
7 545 *Med Rep.* 2017;6:322-8.  
8  
9  
10 546 38. Hasson H. Systematic evaluation of implementation fidelity of complex interventions  
11  
12 547 in health and social care. *Implement Sci.* 2010;5:67.  
13  
14 548 39. Sundler AJ, Lindberg E, Nilsson C, Palmer L. Qualitative thematic analysis based on  
15  
16 549 descriptive phenomenology. *Nurs Open.* 2019;6(3):733-9.  
17  
18  
19 550 40. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation  
20  
21 551 hybrid designs: combining elements of clinical effectiveness and implementation research to  
22  
23 552 enhance public health impact. *Med Care.* 2012;50(3):217-26.  
24  
25  
26 553  
27  
28 554  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 555 **Figure 1: ABCC-tool visualization.** An example of the visualization of the outcomes of the  
4  
5 556 ABCC-tool, in this case for someone with COPD and T2DM. Each balloon represents a unique  
6  
7 557 domain in the ABCC-tool. Green balloons indicate low burden, yellow balloons indicate  
8  
9 558 moderate burden, and red balloons indicate high burden. Grey balloons indicate the score from  
10  
11 559 the previous visit for comparison. A separate “questions” open field shows the additional topics  
12  
13 560 or questions that the patient proposed in the questionnaire.  
14  
15  
16

17 561  
18  
19 562 **Figure 2: Process of using ABCC-tool.** An overview of the cycle of using the ABCC-tool.  
20  
21 563 The cycle starts at the assessing step, and then continues through the visualizing,  
22  
23 564 communicating, and personalizing steps. After the initial evaluation, the visualizing step also  
24  
25 565 facilitates the monitoring step because the balloons from the previous visit are presented in grey  
26  
27 566 shades.  
28  
29  
30

31 567  
32  
33 568 **Figure 3: Overview of study design.** An overview of planned interview moments, specified  
34  
35 569 by the goals of the interview and used frameworks. T0 is the baseline interview prior to actual  
36  
37 570 use, with T1 and T2 following after 3 and 12 months of use respectively.  
38  
39

40 571

41 572

42 573

43 574

44 575

45 576

46 577

47

48

49

50

51

52

53

54

55

56

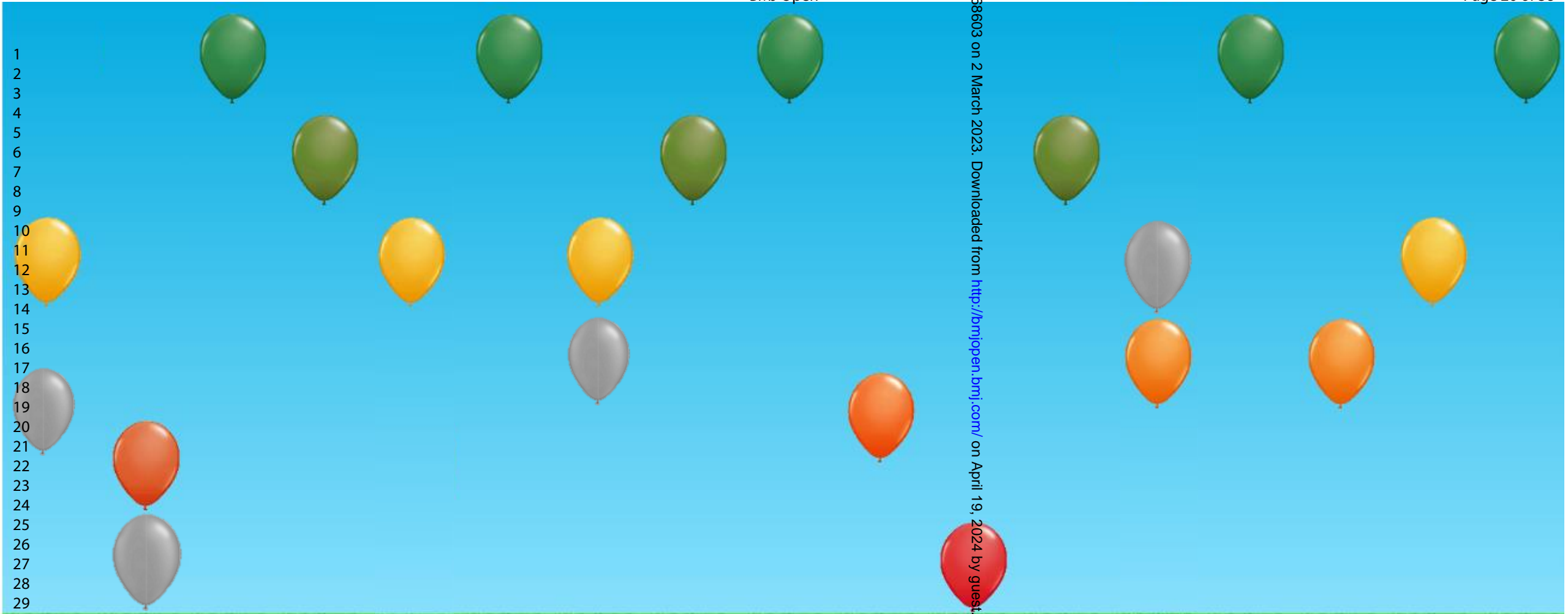
57

58

59

60





32 Lung complaints    Lung attacks    Eating and drinking    Hypo    Worry about blood glucose    Leg and feet (DM)    Physical limitations    Fatigue    Night's rest    Feelings/emotions    Sexuality    Relations and work    Medicines    Weight (BMI)    Physical activity    Alcohol    Smoking

36 Questions:

38 For peer review only: <http://bmjopen.bmj.com/> on April 19, 2024 by guest. Protected by copyright.

40  
41

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41

**Assessing**  
*ABCC-scale*

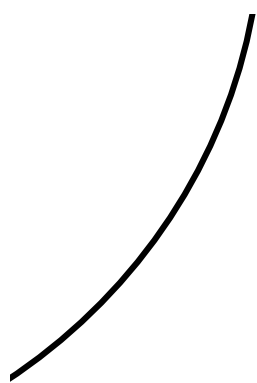
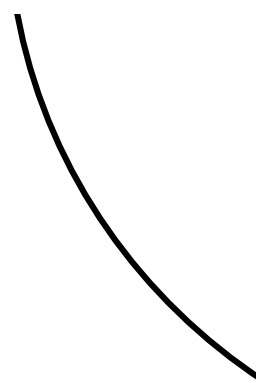
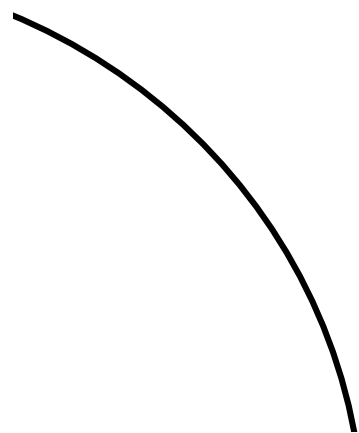
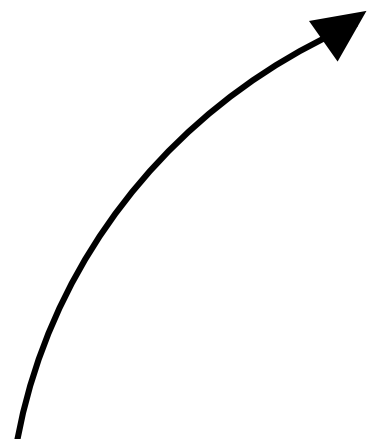
**Personalizing**  
*Goals and individual care plan*

**Visualizing**  
*Balloon diagram*

**Monitoring**  
*Self-management*

**Communicating**  
*Shared decision making*

22-068603 on 2 March 2023. Downloaded from <http://bmjopen.bmj.com/> on April 19, 2024 by guest. Protected by copyright.

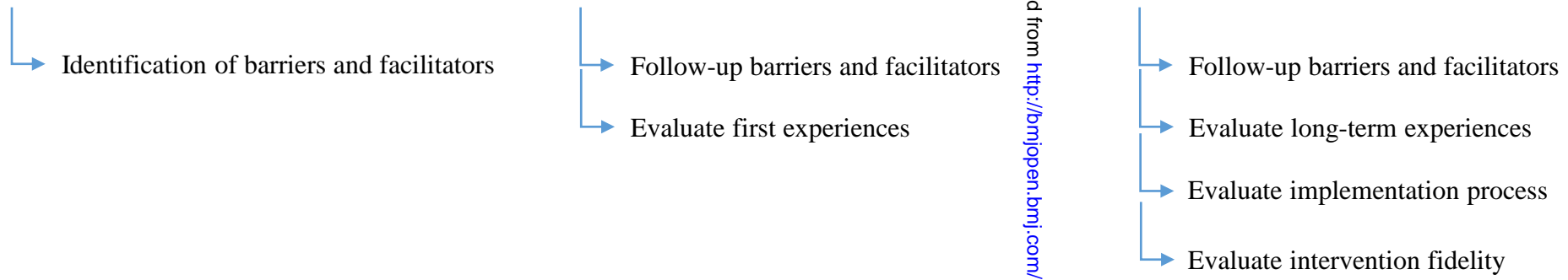


22-068603 on 2 March 2023. Downloaded from <http://bmjopen.bmj.com/> on April 19, 2024 by guest. Protected by copyright.

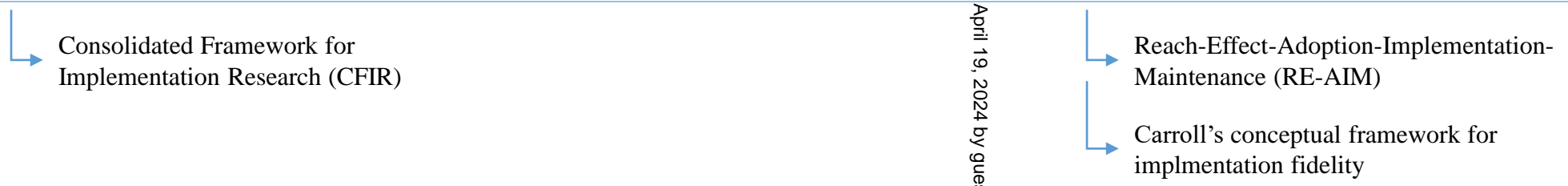
Timeline



Goals



Frameworks



1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41



## 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;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 standards refers 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.
<b>Title and abstract</b>				
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.
<b>Introduction</b>				
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	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.		
<b>Methods: description</b>					
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		
<b>Methods: evaluation</b>					
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		

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

For peer review only

<b>Results</b>					
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		
<b>Discussion</b>					
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)
<b>General</b>					
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
<b>Intervention characteristics</b>			
Intervention source	Stakeholder's perception about development of the 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.
<b>Outer setting</b>			
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	-
<b>Inner setting</b>			
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	-
<b>Implementation climate</b>	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	-
<b>Readiness for implementation</b>	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.
<b>Individual characteristics</b>			
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	
<b>Process</b>			
Planning	The degree to which a scheme or method for implementation is designed in advance, and the quality of these schemes	No	<p>All process-constructs are left out of the interview for several reasons:</p> <ol style="list-style-type: none"> <li>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</li> <li>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)</li> </ol>
<b>Engaging</b>	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](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
<b>RE-AIM framework*</b>	
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). <i>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.</i>
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. <i>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.</i>
Implementation (see fidelity)	The fidelity (adherence) to the key components of the intervention, including deviations and adaptations made and the underlying reasons. <i>This construct is evaluated in more detail using the fidelity framework described below.</i>
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.
<b>Fidelity framework</b>	
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).
<b>Constructs that did not originate from theoretical frameworks</b>	
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).