


# BMJ Open Implementation of a diagnostic decision aid for people with memory complaints and their general practitioners: a protocol of a before and after pilot trial

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## ABSTRACT

**Introduction** Researchers, policy-makers and healthcare professionals often stress the importance of an early dementia diagnosis. Empirical evidence, however, is scarce leading to a lack of consensus on the necessity of diagnosing dementia early. We emphasise the need for a ‘timely’ diagnosis, that is, one that occurs at the right moment for a person with memory complaints and his/her significant other. As the optimal timing differs between individuals, the implementation of shared decision making (SDM), preferably by the general practitioner (GP), as the start of a diagnostic trajectory, could help to determine this timely moment. SDM, however, is rarely practised with respect to dementia diagnoses. Therefore, in the context of the Shared Decision-Making regarding Dementia Diagnosis project, a patient decision aid (PtDA) for ‘timely’ dementia diagnosis in general practice will be developed. This protocol will describe the planned before and after evaluation of its implementation.

**Methods and analysis** In a mixed-methods pilot study, we will investigate decision-making processes and experiences regarding a diagnostic trajectory before and after the introduction of a PtDA for people with memory complaints, their significant others and their GPs. The ‘before group’ will receive diagnostics as usual from their GPs. The ‘after group’ will use the PtDA. We expect the PtDA to increase the level of SDM and to contribute to a timely and personalised diagnostic trajectory. Data will be collected using semistructured interviews, questionnaires and information retrieved from people with memory complaints’ medical records.

**Ethics and dissemination** This study protocol was approved by the Medical Review Ethics Committee of the Maastricht University Medical Centre. The findings will be published in peer-reviewed international journals and presented at conferences. This study was funded by the public funded Dutch Research Institute for Care and Medical Sciences (ZonMw).

**Trial registration number** NCT04531956.

## INTRODUCTION

As a result of a global increase in life expectancy, the prevalence of cognitive impairment and probable dementia will likely rise.<sup>1</sup> Older

## Strengths and limitations of this study

- The mixed-methods design will generate multiple perspective insights on decision-making processes and experiences regarding a diagnostic trajectory of people with memory complaints, their significant others and their general practitioners (GPs). Given the complexity of a shared decision-making (SDM) intervention integrating qualitative data and quantitative data will reveal the working mechanisms of the SDM intervention.
- Semistructured interviews with people with memory complaints, their significant others and their GPs will give an in-depth understanding of decision-making processes and mutual experiences regarding an (early) diagnostic trajectory.
- A convenient consecutive sample of patients is used, in which differences in baseline characteristics could influence the outcome measures.
- GPs included in the study know an intervention that should improve SDM will be implemented. In the preintervention group, they are asked to give care as usual; however, it could be that they change their behaviour because they are primed by our study.

people commonly express anxieties about loss of cognition and of being diagnosed with dementia.<sup>2</sup> This is presumably stimulated by the media and Alzheimer associations as they increase awareness of the dementia burden.<sup>3</sup> As a consequence, general practice will increasingly encounter these worried people and their significant others. Many clinicians, researchers and Alzheimer associations stress the importance of assessing memory complaints early. In some countries, discussions about screening asymptomatic people above 65 years for dementia symptoms are ongoing to be able to diagnose dementia in an early stage.<sup>4</sup> Early diagnosis refers to disclosure as soon as clinical tools indicate dementia.<sup>5 6</sup> However, whether this

approach leads to improvement in terms of the health and well-being of people with memory complaints remains debated.<sup>7-9</sup> On the one hand, early identification of dementia syndrome could enable people with memory complaints and their significant other(s) to plan their future care and life.<sup>6 10-12</sup> Also, future interventions could potentially delay the progression of the disease.<sup>6 13 14</sup> Simultaneously, it may reassure a person with memory complaints that indications of incipient Alzheimer's disease are not present. On the other hand, early identification of dementia has disadvantages. Diagnosing people with dementia early, while no effective cure is available, raises many ethical, healthcare and economic questions.<sup>14 15</sup> That is, an early identification could be burdensome, anxiety-provoking, stigmatising and is even harmful when it raises false expectations.<sup>6 14</sup> Many healthcare professionals, therefore, have expressed their doubts about an early diagnostic trajectory.<sup>16 17</sup> Additionally, screening asymptomatic people above 65 years old in primary care has shown neither harms nor benefits in terms of quality of life, depression or anxiety symptoms and risks of not acting on subjective memory complaints in an early stage might be underestimated because of the under-reporting of these complaints.<sup>18 19</sup>

Taking all these arguments together, early stage identification of dementia or delaying/deferring identification could be considered a preference-sensitive decision.<sup>16 17</sup> That is, the advantages and disadvantages of a diagnostic trajectory are, presumably, valued differently by each person with memory complaints and his/her significant other. Perceptions about dementia and beliefs about possible treatment play a role in how these advantages and disadvantages of diagnostic assessment for dementia are valued and eventually which decision about diagnostic assessment is made.<sup>20</sup> In this respect, it is surprising that the preferences of people with memory complaints, their significant others, and clinicians regarding early identification of dementia have not been fully explored. It is well studied that personal preferences influence healthcare decisions and, consequently, impact the well-being of those affected by these decisions.<sup>16 21 22</sup> The potential advantages and disadvantages of identification of dementia and patients and their significant others' preferences therein should thus ideally be explored at the start of the diagnostic trajectory.<sup>6 14 17 23</sup> A preferred setting to discuss this is a general practice as the general practitioner (GP) is generally the first clinician visited. Additionally, the GP has often known the person for many years and can recognise any significant changes in the person's cognitive functioning. Last, it corresponds with GPs' views on this topic as most of them value a 'timely' diagnosis over an 'early' diagnosis.<sup>16</sup> A timely diagnosis implies that a diagnostic process should be initiated at the right time for the person with memory complaints and their significant others to meet their expectations, needs, and preferences.<sup>21</sup> One way to achieve a timely diagnosis for the person with memory complaints and his/her significant other is shared decision making (SDM).

SDM is generally defined as a dynamic approach in which a healthcare professional informs a patient about the available options and explores the patient's preferences, with the ultimate goal of agreeing on a specific decision.<sup>24</sup> This process requires a continual counselling dialogue between professional and patient and/or proxy decision-maker (eg, significant other).<sup>25</sup> In the case of early identification of dementia, implementing SDM in general practice, at the start of the diagnostic trajectory, could ensure concordance of diagnostic procedures with patients and their significant others' preferences.<sup>6 26-28</sup> Nevertheless, implementing SDM in clinical practice has proven challenging. That is, professionals often express the inability to give a complete and balanced overview of the advantages/disadvantages of a medical decision, because of a lack of skills, tools or time.<sup>29</sup> Moreover, clinicians oppose to SDM implementation as they think they already apply SDM in daily practice or assume that their patients do not want to be involved in decision making.<sup>30</sup> Implementing SDM specific for people with memory complaints is additionally expected to be challenging because people with memory complaints and their significant others sometimes have conflicting views regarding initiating a diagnostic process due to denial, fear or a lack of perceived need.<sup>31</sup> Moreover, participation in SDM requires certain cognitive skills that people with memory complaints might be lacking.<sup>32</sup>

Patient decision aids (PtDAs) have proven to overcome some of these barriers and improve SDM implementation in general practice<sup>33 34</sup> by providing information about the available clinical options, they facilitate discussions about their advantages and disadvantages resulting in better patient engagement in the decision-making process.<sup>33-36</sup> They are effective in achieving informed preferences and in increasing the number of decisions that are in line with patients' preferences.<sup>36 37</sup> The use of PtDAs is also associated with decreased decisional conflict: the state in which a person is uncertain about a decision that is associated with certain risks and different outcomes, as could be the case in deciding on an (early) diagnostic trajectory in case of memory complaints.<sup>36-38</sup> Even though decision aids could facilitate a personal, patient-centred approach in the diagnostic trajectory of memory complaints, they are rarely applied.<sup>27 28 33 34</sup> An exception is a recently developed PtDA for applying biomarkers in memory clinics.<sup>39</sup> However, to find the right timing to start the diagnostic process and to optimise conversations about the advantages and disadvantages of early identification dementia, a PtDA for use in the general practice is needed.<sup>6 14 17 23</sup> The objective of the Shared Decision-Making regarding Dementia Diagnosis (S-DeciDeD) study is, therefore, to develop, implement and evaluate a PtDA using a systematic approach for use in general practice, one which facilitates SDM regarding a timely diagnostic trajectory for people with memory complaints.

This paper aims to describe the study protocol for the pilot evaluation of the S-DeciDeD PtDA for people with memory complaints in general practice.

## Study objectives

The study objectives are to (1) describe and explore the decision-making process (eg, perceived SDM by people with memory complaints and their GPs) before and after implementing a PtDA and to (2) assess to which extent and how a PtDA influences the decision-making process for a diagnostic trajectory in people with memory complaints and their significant others. We expect that implementing a PtDA in general practice will lead to higher levels of perceived SDM.

## METHODS

### Study design

This pilot trial will use a before-and-after mixed-methods design. In the before group (BG), GPs will execute care as usual in the decision-making process for a diagnostic trajectory for memory complaints. In the after group (AG), a PtDA will be added to the decision-making process provided by the GP. The rationale for this design is as follows. First, it maximises comparability between GPs as they will participate in both the before and after period of the study. Second, GPs will be able to reflect on their practice preintervention and postintervention. Third, it allows and facilitates the implementation of the PtDA in all interested GP practices. Fourth, the mixed-methods approach is used to gain a broad and in-depth understanding of the issues important for people with memory complaints, their significant others, and the GPs involved in the decision-making process.<sup>40</sup> We are taking this approach to fully unravel the complexity of the decision-making process for a diagnostic trajectory for memory complaints and of the PtDA.<sup>6 29 30</sup> Last, the use of a pilot trial allows us to explore if the proposed methods are feasible to assess decision-making processes in general practice before and after implementation of a PtDA. This could help plan and execute a larger definitive trial to investigate the effectiveness of using a PtDA in general practice for people with memory complaints and their significant others.<sup>41</sup>

### Setting

The study was developed by Maastricht University Medical Centre (MUMC+) in close collaboration with Radboud University Medical Center Nijmegen (Radboudumc Nijmegen). The participating GPs, people with memory complaints and their significant others will be recruited from general practices located in the southeastern part of the Netherlands.

### Participants

#### Patient involvement

Before the start of the study, a client panel of the Alzheimer Centre Limburg (ie, a panel consisting of people with dementia and their significant others) was asked to reflect on the research design. During the study, people with memory complaints and their significant

others will be closely involved in the development and implementation of the PtDA.

### Recruitment and study participants

First, the researchers will approach GPs working in the south-eastern part of the Netherlands with an information letter about the study. No specific inclusion and exclusion criteria have been formulated for the GPs. GPs who want to participate will be asked to return an application form to the research team. Subsequently, the research team will then provide participating GPs with study material (patient application forms, information letters, and informed consent forms). GPs will be asked to recruit patients with memory complaints during an inclusion period of 6 months in both the BG and AG. In the BG, the GPs will inform potential participants about the study after a decision about a diagnostic trajectory (ie, to wait and see, undergo diagnostic testing by the GP, or referral to a medical centre) has been made. Patients can be included up to a maximum of 3 months after a decision has been made. Significant others of people with memory complaints will be asked to participate as well; their participation is preferred, but not required. Significant others are obtained by asking the person with memory complaints to name someone closely involved in the decision-making process on diagnostic assessment (eg, spouse, child, other close relatives or friends) The inclusion and exclusion criteria of the study are shown in [box 1](#). Participants are initially assessed for eligibility by their GP. If an eligible participant is interested in the study, the GP will send his/her contact details to the researchers. The researchers will contact the potential participant to provide detailed information about the study. Eligible participants will sign informed consent forms before participation. The inclusion/consent procedure in the AG will be finalised based on the developed intervention in a later stage of the study. Data collection in the BG is expected to last from January 2021 to September 2021. In the AG, data collection is expected to last from October 2021 to June 2022. Patients will be selected using convenience sampling. Patients will receive a small incentive for their participation as well as GPs.

Handling of personal data will be in accordance with the Dutch Personal Data Protection Act and Medical Research (Human Subjects) Act.

### Intervention

The intervention will consist of implementing a PtDA in general practice. The PtDA will be developed in line with the systematic development process specified by the International Patient Decision Aids Standards.<sup>42</sup> The development of the PtDA runs parallel to the inclusion of participants in the BG. Before the start of the development process, we will explore stakeholders' opinions and experiences with the decision-making process and map the current diagnostic trajectory in general practice. This will be done by conducting interviews with patients, significant others, and GPs about their experiences and considerations

**Box 1 Inclusion and exclusion criteria of the Shared Decision-making regarding Dementia Diagnosis study****Person with memory complaints**

## Inclusion criteria

- ▶ Person has visited the general practitioner because of memory complaints no longer than 3 months ago (noticed by the person, a significant other and/or the general practitioner).
- ▶ Person is above the age of 60.
- ▶ Person is able to complete baseline assessments.
- ▶ Person must have the decisional capacity to provide informed consent.
- ▶ Person must give written informed consent prior to participation.

## Exclusion criteria

- ▶ Person has communication/language/comprehension/literacy or (severe) hearing problems.
- ▶ Person has had a severe mental illness in the last 12 months, such as schizophrenia, depression, or a bipolar disorder not otherwise specified.
- ▶ Person has a life-threatening comorbid illness.

**Significant other (if present)**

## Inclusion criteria

- ▶ Significant other is able to complete baseline assessments.
- ▶ Significant other must have the decisional capacity to provide informed consent.

## Exclusion criteria

- ▶ Significant other has communication/language/comprehension/literacy or (severe) hearing problems.
- ▶ Significant other has had a severe mental illness in the last 12 months, such as schizophrenia, depression or a bipolar disorder not otherwise specified.

**General practitioners**

No inclusion or exclusion criteria.

in the (early) diagnostic trajectory. Furthermore, data on reasons for encounter, diagnostic procedures and referrals in general practice will be analysed with help of the practice-based research network Family Medicine Network (FaMe-net).<sup>43 44</sup> Lastly, a systematic integrative review will be conducted about the preferences and needs of people with memory complaints, and their significant others, and GPs regarding the timing of dementia diagnosis. For the development of the PtDA, we will partner with people with memory complaints, their caregivers and GPs (ie, a steering group). With help of this steering group, the scope of the PtDA will be refined and their feedback will guide the content and format of prototypes. This will be done in several workshops with the steering group.

Finally, the patient decision-aid will be pilot-tested with help of a test panel. Its usability, language and format will be rated. Based on the pilot, GPs will be instructed on how to best deliver the PtDA to the patient, these instructions will be personalised in case needed. More information on the development of the PtDA can be found in online supplemental appendix.

**Outcome measures**

This before-and-after study will focus on accomplishing a complete understanding of the decision-making process

for a diagnostic trajectory in case of memory complaints before and after implementing a PtDA in the general practice. To accomplish this complete understanding, five aspects will be focused on: (1) the course of the decision-making process, (2) outcome of the decision-making process, (3) experiences during the decision-making process, (4) the perceived SDM and preferences therein and (5) decisional conflict (see [table 1](#)). In the most cases, a significant other is closely involved in the decision regarding the diagnostic trajectory. Therefore, this study will map the experiences and decisional conflict of both the person with memory complaints and a significant other (preferably separate interviews will be conducted). Interviews will be conducted by a trained research assistant or one of the main researchers. Qualitative measures integrated with quantitative measures will be used to achieve cross-validation or triangulation of data from multiple sources<sup>40</sup>:

1. The course of the decision-making process will be explored through retrospectively studying the number of consultations needed to achieve the final decision and through studying 'free text' notes in the medical record of the person with memory complaints. Data from these notes will be extracted with a data extraction form designed to extract signs of shared-decision making. The data extraction sheet is based on the SDM model.<sup>45</sup>
2. The outcome of the decision-making process, that is, to wait and see, undergo diagnostic testing by the GP, or referral to a medical centre will also be obtained from the medical record of the person with memory complaints.
3. The decision-making process in general practice will be explored with semistructured interviews (by telephone or face to face) with people with memory complaints and their significant others. Questions will focus on their experiences, considerations, preferences and expectations during the decision-making process. Preferably patients and their significant others are interviewed individually.
4. To assess SDM during the decision-making process, people with memory complaints (and their significant others) will be interviewed about their experienced level of SDM and preferences regarding SDM. Their GPs will be asked to complete questionnaires about the level of SDM and their self-efficacy regarding SDM.
  1. The level of SDM will be assessed by using the Dutch version of the SDM Questionnaire- Doc (SDM-Q-Doc).<sup>46</sup> This 9-item SDM-Q-Doc focuses specifically on the GP's perspective of the SDM process. The questionnaire has six-level response options (0=completely disagree to 5=completely agree), where higher scores indicate more SDM.<sup>46</sup> The scale has been shown to have good internal consistency and acceptance and acceptable-to-good convergent validity in a sample of physicians.<sup>46</sup>
  2. Self-efficacy regarding SDM will be assessed via a Visual Analogue Scale.<sup>47</sup> GPs have to indicate the

**Table 1** Overview of the measures, components, methods and instruments of the S-DeciDeD study

Measure	Components	Method and instruments
1.Course decision-making process	<ol style="list-style-type: none"> <li>No of consultations</li> <li>'Free text' notes in medical record regarding the decision-making process</li> </ol>	<ol style="list-style-type: none"> <li>Medical record PMC</li> <li>Thematically analysing medical record PMC with help of a data extraction sheet</li> </ol>
2.Outcome of the decision-making process	Final decision (ie, to wait and see, undergo diagnostic testing by the GP, or referral to a medical centre)	Medical record PMC
3.Decision-making process in general practice	<ol style="list-style-type: none"> <li>Experiences, considerations, expectations and preferences PMC</li> <li>Experiences, considerations, expectations, and preferences SO</li> </ol>	<ol style="list-style-type: none"> <li>Semistructured interview</li> <li>Semistructured interview</li> </ol>
4.Shared decision-making (SDM)	<ol style="list-style-type: none"> <li>Experience SDM PMC</li> <li>Experience SDM SO</li> <li>Level of SDM indicated by GP</li> <li>Level of self-efficacy regarding SDM indicated by GP</li> </ol>	<ol style="list-style-type: none"> <li>Semistructured interview</li> <li>Semistructured interview</li> <li>SDM-Q-Doc</li> <li>Self-efficacy VAS</li> </ol>
5.Decisional conflict	<ol style="list-style-type: none"> <li>Decisional conflict experienced by PMC</li> <li>Decisional conflict experienced by SO</li> </ol>	<ol style="list-style-type: none"> <li>Semistructured interview</li> <li>Semistructured interview</li> </ol>
6.Characteristics of people with memory complaints and significant others	Demographic data	<ol style="list-style-type: none"> <li>Baseline questionnaire with questions on demographics</li> <li>Medical record PMC</li> </ol>
7.Characteristics GP	Contextual factors related to the GP	GP practices will be contacted to provide information on location, years of experience GP, and the composition of the general practice.

GP, general practitioner; PMC, person with memory complaints; S-DeciDeD, Shared Decision-making regarding Dementia Diagnosis; SO, significant other; VAS, Visual Analogue Scale.

level of SDM during the last consultation with the person with memory complaints (anchored by—no SDM—complete SDM) and their self-efficacy regarding SDM (anchored by—not competent at all—very competent) after the last consultation.

- Decisional conflict of people with memory complaints and their significant others will be explored in a semistructured interview (by telephone or face to face). The questions will focus on uncertainty regarding the choice made, factors contributing to this uncertainty and the perceived effectiveness of the decision.

#### Other measures

- A baseline questionnaire in combination with the medical record of the person with memory complaints will be used to assess demographic features of people with memory complaints and their significant others.
- The characteristics of GPs that will be collected are the location of the general practice (rural or urban), the composition of the general practice (number of GPs and general practice-based nurses), years of experience each GP has with the population (patients with memory complaints), gender and age.

#### Sample size

Given the dependence between patients and their GPs in our sample, clustering of patients per GP was taken into account in sample size calculations. Clusters were

expected to include at least two people with memory complaints and intraclass correlation to be 0.05 or lower.<sup>48 49</sup> To achieve power of 0.8 and two-sided testing at 0.05, 35 GPs are required.

We, therefore, aim to include between 30 and 40 GPs in our study which seems to be a realistic number based on a previous (comparable) study.<sup>50</sup> This should result in recruiting around 70 patients (with or without significant other).

For the qualitative component of the study, it is expected that interviews with 15–30 patients, with or without their significant other will be sufficient to reach data saturation (ie, the point at which interviews reveal no new information or insights). Participants will be asked to participate in an interview based on the outcome of the decision-making process (ie, to wait and see, undergo diagnostic testing at the GP, be referred to a medical centre for advanced diagnostic testing). In this way, we can ensure that each 'choice category' is represented in the selective sample. From those patients not selected for the interviews, only qualitative data from their medical journals (eg, free text notes) will be analysed. This procedure will be the same in the BG and AG.

## Data analysis

### Quantitative analysis

Descriptive analyses will be conducted on the socio-demographic characteristics of people with memory complaints, their significant others and GPs. To assess the decision-making process, descriptive analyses will be conducted on: the number of consultations before the final decision, final decision (ie, number of decisions in each 'choice category'), level of SDM and level of self-efficacy regarding SDM as indicated by GPs. Furthermore, multiple regression analysis will be performed to investigate: (1) whether sociodemographic characteristics or characteristics of the decision-making process are related to the outcome of the decision-making process or to the level of SDM and (2) whether the level of SDM is associated with the outcome of the decision-making process. A random effect multilevel analysis will be used to assess changes in the decision-making process before and after implementing the PtDA while taking clustering at the GP level into account. Baseline characteristics will be added as confounders in case of observed differences in the before and AG. Since the participation of significant others is not required, differences in outcome measures between participants participating with and without significant others will be explored. In case differences are found, this will be taken into account in the main analysis. Integration of these analyses with qualitative measures will help explain these results. All analyses will be conducted using SPSS version 25. In case of missing data, GPs will be contacted to retrieve the missing values.

### Qualitative analysis

Qualitative methods will be used to analyse data regarding experiences in the decision-making process, SDM and decisional conflict. Interviews will be audiotaped and transcribed verbatim. Because of the explorative nature of the study, we will conduct an inductive thematic analysis.<sup>51</sup> Two researchers will separately code transcripts of the interviews. The thematic analysis will consist of an iterative process of several steps. First, two researchers will familiarise themselves with the data by (re) reading the transcripts and creating initial codes. Second, codes will be clustered into categories (axial coding), when they describe or relate to the same phenomena. Third, codes can be renamed or reassigned, after which categories can be combined and themes refined (selective coding). Fourth, the categories and themes will be discussed with the research team and will be re-evaluated. As a final step, consensus will be reached on the categories and main themes' relevance and meaning.<sup>52</sup> Atlas.ti will be used to support the analyses. Data from the interviews with people with memory complaints and their significant others will be incorporated in the same thematic structure. This way we can show possible differences and similarities in their experiences of the decision-making process. The recommendations outlined in the COnsolidated criteria for REporting Qualitative research (COREQ) criteria will be followed in reporting the results.<sup>53</sup>

### Mixed model analysis

Integration of quantitative and qualitative research methods will be applied during data collection as well as during analyses. During the data collection, attention will be paid to 'building' and 'merging'.<sup>54</sup> Building will be applied by selecting patients for semistructured interviews based on quantitative data such as age, gender, and the final outcome of the decision-making process. Merging will be applied through tailoring topic lists for the semistructured interviews to the personal situation of patients and their significant others, a task which will be accomplished with the help of information from their medical record. During data analyses, 'merging' and 'embedding' will be applied (ie, qualitative data will be used to explain identified patterns in quantitative outcome measures which will provide insight into the working mechanisms of the PtDA).<sup>55 56</sup> Both the qualitative and quantitative data sets will be analysed independently and concurrently. Subsequently, the data will be assessed for complementarity. This will include using the qualitative data to achieve a more in-depth and complete understanding of the course of the decision-making process before and after implementing a PtDA.

In conclusion, this study aims to examine the decision-making process regarding starting a diagnostic trajectory for memory complaints before and after implementing a PtDA. Through using a mixed-method approach, we hope to unravel the complexity of this decision-making process and investigate the potential impact of implementing a PtDA on this process. The results of this pilot study could help plan and execute a larger definitive trial to investigate the effectiveness of using a PtDA in general practice for people with memory complaints and their significant others. Specifically, the results will inform to which extent these study methods and procedures are feasible to investigate decision-making processes in general practice.

### Ethics and dissemination

Care as usual will most likely not be influenced in the BG of the S-DeciDeD project. Only a small-time investment will be required from GPs and patients: 5 min for completing the questionnaires and twenty minutes for participating in the interview. The protocol of the BG has been approved by the Medical Review Ethics Committee (MEC) of the MUMC+ in the Netherlands, number 2018–0333. Data collection in the BG will start at the beginning of 2021.

The protocol for the AG will be submitted to the MEC after the development of the PtDA as judgement should include full information on this novel intervention. The S-DeciDeD project is part of the national Memorabel programme funded by ZonMw. Any important protocol modifications will be submitted to the MEC of Maastricht University and ZonMw for approval.

Furthermore, as Maastricht University aims to become a Findable, Accessible, Interoperable and Re-usable university, the data will also be published on DataverseNL (<https://dataverse.nl/>). This is a website where researchers can upload their anonymous data with

restricted access, which allows other researchers to use the data or replicate the findings after receiving permission from the S-DeciDeD project. Finally, the findings will be published in peer-reviewed international journals and presented at conferences and in one dissertation.

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**Contributors** CW, RWHMP, CD and MP initiated the S-DeciDeD project and provided ZonMw (funder of the S-DeciDeD project) with a detailed and elaborate study protocol. IL was responsible for the recruitment of general practitioners and for obtaining ethical approval from the MEC of Maastricht. IL rewrote the study protocol for publication in BMJ Open under the supervision of CW, MP, RWHMP and CD. JM, TvdW, MdV, FRV, RH and MOR are part of the project team and read and approved the manuscript.

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