How Can Informed Choice in Mammography Screening Be Improved? Development and Evaluation of a Decision Aid

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Summary

Background. Most women in Germany have to decide whether they want to attend the Mammography Screening Programme to which they are invited once they turn 50. Informedness is an ethical requirement for decisions on screening but research shows that informed choice is not sufficiently realised. Decision aids are a promising class of interventions to realise informed choice as they improve knowledge, clarify values, and improve behavioural implementation of and satisfaction with a decision. However, there is a knowledge gap regarding which components of decision aids are effective. *Manuscript 1* provides evidence for knowledge increase through use of crowd-figure-pictograms. Prior to this research project, no decision aid existed that aimed at average risk women in the target age group of mammography screening and was evaluated in a randomised controlled trial. Most previous studies on decision aids only looked at their immediate effect and did not follow-up on whether the decision was implemented and which medium-term effects the decision aid had on knowledge and post-decisional satisfaction. Therefore, a twofold gap remains: We lack (1) a decision aid appropriate for women invited to the German Mammography Screening Programme and (2) evidence on medium-term effects of decision aids.

Methods. The main research project of this dissertation developed a decision aid for women invited to the German Mammography Screening Programme for the first time and evaluated it in a randomised controlled trial with a 3-month follow-up. Acceptability and effectiveness of the decision aid including possible moderators (eHealth literacy and education) were evaluated. Details of the study protocol are presented in *Manuscript 2*. To be able to assess all relevant outcomes, two other research projects were employed for instrument development and validation. Development and validation of a questionnaire assessing informed choice are described in *Manuscript 3*; translation and validation of a measure for eHealth literacy are described in *Manuscript 4*.

Results. Women rated the decision aid as acceptable. *Manuscript 5* provides evidence of the effectiveness of the decision aid: Women who had received the decision aid were more likely to make an informed choice, to have higher knowledge, and to have lower decisional conflict. Uptake was not affected. *Manuscript 6* shows that the effect of the decision aid on knowledge was moderated by neither eHealth literacy nor education level.

Conclusions. This dissertation was the first to develop and systematically evaluate a decision aid for the German Mammography Screening Programme. To achieve this, it integrated the results of three related research projects for instrument development and testing of crowd-figure-pictograms. The developed decision aid was acceptable to its users and effective in increasing the proportion of informed choices. Knowledge was also increased through the decision aid irrespective of eHealth literacy or education level. Thus, the decision aid developed in this project is an important support tool for women deciding whether to participate in the Mammography Screening Programme.

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- **Manuscript 1**

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- **Manuscript 2**

  Reder, M. & Kolip, P. (2015). Does a decision aid improve informed choice in mammography screening? Study protocol for a randomized controlled trial. *BMC Women's Health*, 15, 53. doi: 10.1186/s12905-015-0210-5.

- **Manuscript 3**

  Reder, M., Berens, E.-M., Spallek, J., & Kolip, P. (2019). Development of the Informed Choice in Mammography Screening Questionnaire (IMQ): Factor structure, reliability, and validity. *BMC Psychology*, 7, 17. doi: s40359-019-0291-2.

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  Reder, M., Soellner, R., & Kolip, P. (2019). Do women with high eHealth literacy profit more from a decision aid on mammography screening? Testing the moderation effect of the eHEALS in a randomized controlled trial. *Frontiers in Public Health*, 7, 46. doi: 10.3389/fpubh.2019.00046.

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List of Abbreviations

CFA – Confirmatory Factor Analysis

DA – Decision Aid

EFA – Exploratory Factor Analysis

eHEALS – electronic Health Literacy Scale

EnTeMa – Entwicklung und Testung einer Entscheidungshilfe zur Teilnahme am Mammographie-Screening-Programm [Development and Testing of a Decision Aid for Mammography Screening]

IMQ – Informed Choice in Mammography Screening Questionnaire

InEMa – Informierte Entscheidung deutscher und türkischer Frauen bei der Teilnahme am Mammografie-Screening-Programm [Informed Choice of German and Turkish Women for Participation in the Mammography Screening Programme]

IPDAS – International Patient Decision Aids Standards

IRT – Item Response Theory

MSP – Mammography Screening Programme in Germany

RCT – Randomised Controlled Trial

1. Introduction

In women worldwide, breast cancer is the most common form of cancer and the leading cause of cancer related mortality [1]. One in eight women is affected by breast cancer during her lifetime [2] and this cancer causes a huge burden of disease. Mammography screening is supposed to detect breast cancer early and, thus, to decrease morbidity and mortality. Whether mammography screening is recommendable to achieve this goal has been hotly debated over the past decades [3]. Evidence regarding the benefit of mammography screening is mixed: Mammography screening leads to an estimated 15 % reduction in breast cancer mortality and simultaneously causes about 30 % overdiagnosis and overtreatment without evidence for all-cause mortality benefit [4]. Nevertheless, in Germany, the Mammography Screening Programme (MSP) has been offered nationwide to women aged 50 to 69 since 2009 [5]. In a situation where an intervention with controversial beneficiality is offered to a healthy population, informed choice becomes more important than ethical considerations alone would dictate.

Informed choice constitutes a decision that relies on relevant knowledge, is consistent with one's values, and leads to decision-congruent action [6]. Informed choices are an ethical and legal requirement [7, 8] and have a positive influence on quality of life [9]. Contrary to this importance, research shows that an informed choice is not achieved in a large proportion of mammography screening decisions [10–12]. Posing a possible solution, decision aids (DAs) are a promising class of interventions to achieve informed choices [13]. They have been shown to improve knowledge, clarify values, and lower decisional conflict [13–16]. While it is well established that DAs increase informed choices and knowledge, controversy surrounds which components or combinations of components of a DA are effective, through which processes these work, or in which target population they are effective (e.g., regarding education level and eHealth literacy). Unfortunately, not many DAs for mammography screening exist and even fewer have been systematically evaluated. Furthermore, many DAs do not target the screening age group (50 to 69 years) or an average risk population. Before this project, no DA for the MSP that was evaluated in a randomised controlled trial (RCT) existed.

This dissertation, in its main research project, focuses on the development and evaluation of a DA for women invited to the MSP for the first time. To achieve these two goals, this dissertation had to envelop three other research projects (or at least parts of these) to (1) assess the effect of crowd-figure-pictograms, (2) develop and validate an instrument to assess informed choice, and (3) translate and validate an instrument to assess eHealth literacy. These three projects were necessary to answer the preliminary research questions and methodological challenges that had to be solved before the main project could be undertaken. Successful development of an evidence-based effective DA allows – once it is accessible to the public – an increase in informed choices and, thus, a reduction in some of the negative consequences of the MSP that stem from insufficient

informedness. Furthermore, the results allow insights into how a DA influences informed choices and which factors moderate the effectiveness of a DA.

The Background Section describes the theoretical foundation for this research and introduces *Manuscript 1* on the effect of crowd-figure-pictograms on knowledge acquisition. The Methods Section describes the development process of the DA as well as study procedures, outcomes, and statistical analysis of the evaluating RCT. *Manuscripts 2, 3, and 4* on the study protocol and different measurement instruments (Informed Choice in Mammography Screening Questionnaire [IMQ] and eHealth Literacy Scale [eHEALS]) are introduced. The Results Section delineates the findings on the acceptability, the effectiveness (*Manuscript 5*), and the moderators (*Manuscript 6*) of the DA. Finally, the Discussion Section integrates the results of this RCT with those of previous research including the studies described in *Manuscripts 1, 3, and 4*, describes practical as well as theoretical implications, gives an overview of future research, and draws conclusions.

2. Background

2.1. Mammography Screening

In women in Germany [17] as well as worldwide [1], breast cancer is the most common cancer causing a high burden of disease. Mammography screening is the screening of choice to detect breast cancer. Its clinical rationale is to reduce mortality and morbidity through earlier detection of breast cancer. In Germany, introduction of the MSP was decreed in 2002 [5]. In 2005, the first screening units started their work and since 2009 the MSP has been available to women nationwide. Women aged 50 to 69 are invited to the MSP every 2 years with a specified appointment [18]. As a result, women have to make a choice about whether they want to attend the MSP once they receive the invitation.

There has been a lot of controversy surrounding whether mammography screening – and accordingly MSP attendance – is beneficial. The current Cochrane Review indicates that women participating in mammography screening are less likely to die of breast cancer but the exact size of the effect remains uncertain [4]. Furthermore, there is a lack of evidence for all-cause mortality benefit [4]. Mammography screening leads to an estimated 15 % reduction in breast cancer mortality while it causes about 30 % overdiagnosis and overtreatment; for every life prolonged, 10 women are unnecessarily treated and 200 experience a false-alarm [4]. Overdiagnoses are detected abnormalities meeting the pathologic definition of cancer, but either do not progress or progress so slowly that the individual dies from another cause before the cancer causes symptoms [19, 20]. As women age, their competing risk for death increases, making overdiagnosis more likely [19]. This is why screening programmes stop at a certain age. Smith-Bindman et al. [21] report a lifetime risk of a false-positive screening result of 20 % to 25 %, which in turn can have adverse psychological effects [22]. A false-positive screening mammogram may lead to anxiety,

biopsies for further diagnostics, and psychological distress lasting for as long as 3 years [19, 23–25]. Six months after a false-positive result, women reported changes in existential values and inner calmness comparable to those with a true-positive result [25]. Another inherent problem of screening is that – since there is no diagnostic gold standard – it misses cases (false-negatives) and thus leads to false-reassurance [19, 21, 23]. Furthermore, mammography screening, by its nature, misses the most aggressive cancers (because these develop between screenings rounds and cause symptoms leading to a breast cancer diagnosis) and is more likely to detect slow growing cancers than a clinical diagnosis [26]. Thereby, earlier detection can lead to a more favourable survival expectation at the time of diagnosis, even if screening has no effect on the time of death (lead time bias [26]).

In addition to the general question of beneficiality, in a population-based screening programme the question arises as to which age group should be invited at which intervals. The divergent ranges of screened ages and screening intervals in various countries again suggest uncertainty regarding the beneficiality. Of 19 International Cancer Screening Network countries, 13 start screening at age 50, two at age 45, and four at age 40 while the end of the screening age varies from 64 to 74 [27]. The World Health Organization [28] recommends mammography screening for women aged 50 to 69 every 2 years under the condition that decision making strategies are implemented that ensure value congruent choices. The European Union has similar recommendations regarding screening age and interval, while the American Cancer Society recommends mammography screening annually starting at age 40 [26].

This leads to the paradoxical situation where there are screening programmes operating, even though it is not clear whether they are beneficial. This is especially problematic because many women overestimate the usefulness of mammography screening in lowering breast cancer mortality and are not aware of false-positives or overdiagnosis [29]. Additionally, the MSP has opportunity costs (e.g., time of participants and staff); these resources could be used for health interventions with a better risk-benefit ratio.

2.2. Informed Choice in Mammography Screening

Informed choice – a decision that is based on sufficient knowledge, consistent with one's values, and then implemented [30] – is of special importance in mammography screening both from an ethical and a legal perspective. The reasons for this are described in the following. First, it is unclear whether benefits outweigh harms [4, 31] as described above. In accordance, women should be enabled to make informed choices through adequate communication of information about mammography screening [31] and not simply be recommended to take part. Related to this is the second point: Weighing benefits against harms is always a value judgment (regardless of what the risk-benefit ratio looks like), thus, no correct answer can be determined [3] making the decision preference sensitive [18]. Third, for any decision, the ethical principles for communication

are those that generally apply to biomedical ethics [32]: autonomy, non maleficence, beneficence, and justice [33]. Informed choice is ethically founded on these 4 principles [8]. Additionally, a legal obligation of informed consent before medical interventions is anchored in most legislations [8]. Accordingly, provision of all relevant information (including important harms) through health authorities is necessary [3]. Withholding information is a violation of the principle of autonomy [7]. Fourth, being well informed also has the potential to alter the risk-benefit ratio since many complications are caused by a lack of informedness and not by the screening process itself. For example, symptoms may be ignored because of a false sense of security following a negative result or health service staff may be blamed unfairly for inherent screening characteristics such as false-positives [34]. Understanding the likelihood of false-positive screening results could also reduce the stress experienced following a positive result since the woman would know that the likelihood of breast cancer is still low [35]. Fifth, health services aimed at healthy individuals – like the MSP – make informed choice even more crucial [35]. From an ethical perspective, population-based screening programmes complicate informed choice because the targeted individuals have no symptoms and because the locus of initiative is the healthcare system not the individual [3, 32, 36]. Nevertheless, individuals are confronted with a complex decision they cannot avoid [36].

For the above described reasons, uninformed compliance [37] is a major public health problem and informed choice can be categorised as an important public health issue [38]. This is also reflected in informed choice being advocated as a health care quality marker by many organisations (e.g., the Institute for Quality and Efficiency in Health Care [39]). Apart from ethical and legal considerations, the following guidelines regard informed choice in mammography screening. The European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis devote a whole chapter to communication about screening (Chapter 12 [32]) and state that appropriate and unbiased information is to be provided to women enabling them to make an informed choice. The German National Cancer Plan [40] states as one aim the improvement of information for early detection measures of cancer to achieve informed choices (though it has to be noted that it states an improvement in uptake rate as a secondary aim – and these aims may be contradictory).

Research shows that informed choice is not achieved in a large proportion of mammography screening decisions even though estimates vary widely: Internationally, Mathieu et al. [10] report that 48 % of choices are informed choices, whereas van Agt et al. [11] report 88 %. For Germany, Berens et al. [12] report 27 %. Furthermore, knowledge about mammography screening is often flawed. More than 90 % of women overestimate breast cancer mortality reduction as a result of mammography screening; more precisely, 30 % estimate the reduction in breast cancer mortality per 1000 women after 10 years of screening to be 100 to 200 (1 woman per 1000 is the correct answer [29]). Domenighetti et al. [41] report that 62 % assumed mammography screening reduced

breast cancer mortality by half and in a study by Chamot & Perneger [42], only 19 % estimated breast cancer mortality reduction correctly. Webster & Austoker [43] found that only 36 % knew the lifetime risk of breast cancer. Alarmingly, around half of women think screening prevents breast cancer (45 % in the United Kingdom [43] and 56 % in Germany [44] have been reported) and 68 % think that it reduced the risk of contracting breast cancer [41]. The likelihood of receiving a false-positive result is largely underestimated (only 2 % estimated this correctly [45]). Having previously attended mammography screening did not increase knowledge [43]. In *Manuscript 1*, we assessed baseline knowledge levels in university staff and students in Sheffield, United Kingdom [46]. While it has to be noted this was not a representative sample of university staff and students [46], the responses still give an indication of possible problem areas in informedness. Only 24 % reported the correct number of false-alarms and 4 % knew how many women attending mammography screening were likely to be diagnosed with breast cancer [46]. A quarter thought there would be no overtreatments [46]. 3 % knew the number of deaths (correct answer category 1 to 4 deaths) avoided per 2000 women screened regularly for 10 years while most women thought that 91 to 245 deaths would be avoided [46]. This is problematic because women's knowledge of the existence as well as likelihood of important screening outcomes is essential for informed choice [7, 47].

This gap between importance of informed choice and research mostly reporting a lack of informed choice leads to the question of why it is not achieved to a higher degree. There are two possible reasons: (1) information materials may be inadequate and/or (2) women may be unable or unwilling to engage with this information. These reasons will be further elucidated in the following paragraphs.

Current information materials may be inadequate for three reasons: (1) the incompleteness of information, (2) the presentation of information, and (3) the lack of decision support. *Complete information* includes finding a way to communicate scientific uncertainty [48] about the extent of benefits and harms. Information materials often ignore this [7]. More specifically, controversies regarding beneficiality are rarely mentioned in a paternalistic approach [49]. Women often receive biased information that aims to encourage participation and neglects major harms [7] or in which the size of the benefit is either not explained or only as relative risk reduction rather than as absolute risk reduction [49, 50]. Dierks & Schmacke [45] report that 31 % of women did not understand the invitation to the MSP in such a way that they had a choice between participation and non-participation. Consulting health leaflets even tends to increase overestimation of screening benefit [29]. Therefore, the Harding Center for Risk Literacy has strongly advocated improving information materials [51]. In all countries studied (Austria, France, Germany, Italy, Netherlands, Poland, Russia, Spain, United Kingdom), the age groups targeted by the respective screenings were less informed than younger women, even though older women searched for

more information [29]. Simple messages in the English breast screening programme's information leaflet were frequently not understood [52]: When asked whether screening prevented breast cancer, some women who had responded correctly before seeing the leaflet, gave a false answer afterwards. *Well presented information* is especially important for numeric content because this content is often poorly understood [53]. None of the invitations for mammography screening that Jørgensen & Gøtzsche [49] reviewed included numeric information on overdiagnosis or overtreatment and false-positives were downplayed since they were given as risk per screening round and not cumulative risk after an anticipated screening span of 20 years. Additionally, most leaflets had suggestive headings emphasising benefits [49]. *Decision support* requires stating clearly that a decision is to be made and that there are no wrong choices. One point often criticised is that the MSP invitation comes with a pre-specified appointment. This short cuts the decision step and implies duty to participate [49]. In the MSP, where patients do not see a doctor, there is no easy option to circumvent the use of information materials, even though a dialogue on a one to one basis might be more helpful for decision making. Therefore, well designed information and decision support materials are of tremendous importance.

In addition to information materials being inadequate, women may be unable or unwilling to engage with the information materials for various reasons. First, understanding screening benefits, harms, and their likelihood is difficult [54–56]. Second, a decision may already have been made. Third, due to a lack of time, giving a low priority to the decision, or a general preference for delegating medical decisions to health professionals, women may rather rely on advice or simply follow the suggested appointment. In sum, diverse hindrances to informed choice exist in both materials and targeted women.

2.3. Increasing Informed Choice – A Theoretical Perspective

To improve informedness about mammography screening, a theoretical foundation for intervention development is needed. Two models are of special importance: (1) the descriptive model of informed choice [6] itself, and (2) one of the most widely used predictive models of health behaviour – the Reasoned Action Approach [57].

Descriptive models allow the description and categorisation of health behaviour. As such, the multidimensional model of informed choice [6] can help identify solutions for increasing the proportion of informed choices through indicating the dimensions of informed choice, which are described in the following, as targets. Informed choice constitutes a decision that is based on relevant knowledge, in consistence with individual values and behaviourally implemented (i.e., it can be conceptualised as a 3-dimensional model with the dimensions knowledge, attitude, and behaviour [30]). Marteau et al. [6] developed a measure of informed choice based on this definition for prenatal screening for Down's syndrome (consisting of a knowledge scale, an attitude scale, and a

record of screening uptake) allowing the assessment of both the level of knowledge and the congruence between attitude and screening behaviour [58]. When we classify choices based on these three dimensions, 8 possible combinations result [6], of which 2 are informed: (1) good knowledge, positive attitude, and uptake; (2) good knowledge, negative attitude and no uptake. The remaining 6 combinations are considered uninformed. Michie et al. [59] suggested subdividing the 6 uninformed choice combinations into completely uninformed combinations (poor knowledge and incongruence between attitude and behaviour) and partly uninformed combinations (either poor knowledge and congruence or good knowledge and incongruence between attitude and behaviour). However, the multidimensional model of informed choice does not include the decision/intention – an important predictor of action – as a dimension [35]. Only using intention instead of behaviour as a dimension of informed choice enables us to assess the informedness of a choice before the behaviour occurs [35]. Previous research successfully used the concept of informed choice with intention as third dimension (e.g., Marteau et al. [6]). Michie et al. [59] explicitly suggest a conceptualisation of informed choice as 3-dimensional model with the dimensions knowledge, attitude, and intention. Thus, two factors can be altered to increase the proportion of informed choices: (1) knowledge and (2) intention-attitude-congruence or behaviour-attitude-congruence (depending on the time of assessment).

Predictive models allow the prediction of behaviour (e.g., whether a woman participates in mammography screening). The Reasoned Action Approach (building on its predecessors the Theory of Reasoned Action and the Theory of Planned Behaviour [57]) is taken as a predictive model for the decision process because it can help identify the constructs that can be targeted in the decision process to increase the proportion of informed choices. Furthermore, the multidimensional measure of informed choice is based on this approach [6, 59]. The Reasoned Action Approach reveals the informed choice constructs in their temporal context in the decision process (e.g., attitude precedes intention). In the Reasoned Action Approach, intention predicts behaviour. The intention in turn is influenced by three constructs: attitude, subjective norms, and perceived behavioural control. The relative importance of these constructs varies from person to person and from behaviour to behaviour [57]. Attitude is defined as the tendency to respond with some degree of favourableness to an object, i.e., it has a bipolar evaluative dimension [57]. It is formed through outcome expectancies and outcome evaluation. Instrumental and experiential attitudes towards a behaviour can be distinguished [57]. Subjective norms are the social pressure one perceives to perform a behaviour [57]. They are determined through normative beliefs, which can be split into two entities: (1) descriptive normative beliefs regarding whether important others perform a behaviour; (2) injunctive normative beliefs about important others' approval regarding one's performance of a behaviour [57]. Perceived behavioural control is the perceived capability of performing a behaviour and is determined through control beliefs regard-

ing personal and environmental facilitators or impediments [57]. All beliefs are influenced by a somewhat unclear melting pot of background factors which includes individual constructs (e.g., emotions, perceived risk, past behaviour), social constructs (e.g., education), and information constructs (e.g., knowledge). Accurate information allows an individual to choose a behaviour in line with one's interests but knowledge has no consistent influence on behaviour [57]. Whether a certain background factor influences a particular belief can only be determined empirically [57]. According to the Reasoned Action Approach, the following constructs may be targeted to increase the proportion of informed choice: (1) increase the background factor knowledge, (2) clarify attitude so that its predictiveness of intention is increased, (3) change subjective norms so that a choice according to knowledge and personal attitude is perceived as permissible, (4) increase perceived behavioural control so that a behaviour which one would potentially be willing to perform appears possible and neither intention formation nor performance of this behaviour is hindered.

From the targets identified in these two models, DAs may be effective interventions to increase informed choice both from a descriptive and a predictive perspective. Currently, DAs are the most comprehensive intervention (not requiring personal patient-doctor-communication) to enable informed choices. DAs are defined as interventions expatiating explicit decision making, providing evidence-based information about the benefits and harms of possible options, and helping clarification of value associated with those benefits and harms [13]. Matching the requirements of the descriptive model of informed choice (increasing knowledge and intention-attitude-congruence), a typical DA consists of an information part and a values clarification method helping to determine the desirability of available options through making holistic comparisons based on relevant values [60]. These two targets identified in the descriptive model are similarly implied by the predictive model. Additionally, the Reasoned Action Approach suggests subjective norms and perceived behavioural control as targets. Subjective norms may be modified through the DA clearly stating that a decision is to be made (and not just a norm to be followed) and that there are no wrong choices. The DA also informs about the different options and availability of services, thus, perceived behavioural control may be increased at least to some extent.

The International Patient Decision Aid Standards Collaboration (IPDAS [61]) developed very comprehensive and widely used criteria for DAs which are designed to ensure a minimum level of quality for DAs. These criteria include the dimensions of systematic development [62], providing information about options [8], basing information on scientific evidence [63], balancing the presentation of information [64], presenting quantitative information [65], clarifying values [60], addressing health literacy [66], and establishing the effectiveness of DAs [67]. Similar to the two models described above, these criteria imply the importance of addressing knowledge (through evidence-based information including quantitative information) and attitude (through clarifying

values). Furthermore, they suggest the importance of taking the health literacy of DA-users into account for ensuring its effectiveness.

2.4. Existing Decision Aids

DAs have been shown to be an effective way to support informed choices: they improve knowledge, increase active engagement in decision making, lead to a higher proportion of choices being in congruence with the decision maker's values, lower decisional conflict due to feeling uninformed or unclear about ones values, and increase confidence in and satisfaction with the decision [13–16]. As such, DAs help individuals choose between medically-appropriate healthcare options [68].

Specific to mammography screening, research has similarly shown that DAs are a promising strategy to increase the rate of informed choices [10]. Internationally, many DAs on mammography screening have been developed and systematically evaluated [69]. However, these studies either do not target the age group for which mammography screening is intended [10, 70] or assess only high-risk populations [71, 72]. Additionally, previous studies [10, 14, 70, 73, 74] only looked at immediate effects and did not follow-up on whether the decision was implemented and what long term effects the DA had on knowledge and post-decisional satisfaction. The Inventory of Decision Aids of the Ottawa Hospital Research Institute [75], the criteria of which served as the basis for the qualifying criteria of the IPDAS [76], yields five DAs on mammography screening. These are targeted at women (1) aged 40 [70], (2) aged 70 [10], (3) aged 40 to 49 deciding on age at screening initiation and screening interval [77], (4) with dense breasts [78], and (5) deciding between the options of screening initiation at 40 or 50 [79]. The Cochrane Review on the effectiveness of DAs [13] reports only two DAs for mammography screening (see DAs 1 [70] and 2 [10] described above). None of the five described DAs targets at an average risk population aged 50 to 69 and three do not include having no mammography as an option but instead compare different screening initiation ages, screening intervals, or screening tests [69].

For the MSP in Germany, no RCT-evaluated DA existed at the time this project was conducted [18]. An inventory of German language DAs [80] comprised only 12 RCT-evaluated DAs; none of these was on mammography screening. To our knowledge, only one German DA on mammography screening [81] existed at the time of our study. It was evaluated with a convenience sample of 152 women in a cross-sectional study [81] not meeting IPDAS criteria to a high degree. Furthermore, two sources offer information materials: (1) the Kooperationsgemeinschaft Mammographie, which also offers the MSP; and (2) health insurances [69]. The 2010 brochure of the Kooperationsgemeinschaft Mammographie (at the time our study was conducted, the usual care in terms of information provided with the invitation to the MSP [82]) has been criticised for being insufficient for enabling women to make informed choices [83]. Recently and after the end of our data collection, a paper-based DA was developed by the Institute for Quality and

Efficiency in Health Care [84] but it has not been evaluated in a RCT yet. To summarise, none of the materials for the MSP were sufficiently fulfilling IPDAS criteria [61] or evaluated in a RCT [69].

2.5. Consequences for Developing a Decision Aid

As described in Section 2.4, for the MSP no suitable DA was available. Thus, a DA based on the model of informed choice and the Reasoned Action Approach and according to IPDAS criteria had to be developed. As a fundamental step, the behaviour for which the proportion of informed choices was to be increased and the DA was to be developed had to be defined. According to the Reasoned Action Approach, the following four elements needed to be specified [57]: Participating (action) in mammography screening (target) following the invitation of the German MSP (context) in the next 3 months (time) [35]. From the theoretical considerations in Section 2.3 and the shortcomings of existing DAs in 2.4, the following consequences can be drawn for DA development.

2.5.1. Completeness

Enabling women invited to the MSP to make an informed choice requires informing them about both the existence and the probabilities of benefits and harms [18]. This is especially important to increase knowledge. Gummersbach & Abholz [85] indicate that the lack of effect of the MSP on overall mortality should be included. Only this allows seeing the benefit of the MSP in context. Moreover, information materials should state that a decision for non-attendance is not irresponsible [49]. This may have a positive effect on subjective norms. There is an ongoing discussion about how useful quantitative information in DAs is for the deciding person [86] but numeric information has been shown to lead to a more accurate risk perception than verbal descriptions of probability [87]. From an informed choice perspective, not only the mere existence of a beneficial or adverse outcome but also its probability is important for the decision [88]. Adding a complication to the presentation of risk estimates in general is that these estimates suffer from two types of uncertainty [65]: indeterminacy of future events (aleatory uncertainty) and limitations of the risk information itself (epistemic uncertainty). Ideally, both types should be mentioned in a DA.

2.5.2. Presentation

Optimal presentation of information is essential for a DA to increase knowledge. Everyone experiences cognitive biases when dealing with risk information and the presentation of the information has a large influence on those biases [89]. There is substantial misunderstanding of verbal descriptions of probability with a wide range of over- and underestimation [90]. Numeric information has been shown to be difficult to interpret by the general population [55, 91, 92].

Further, framing effects [16, 93–95] influence decisions. In a study by Honda & Yamagishi [94], 90 % recommended treatment following positive framing compared to 30 % following negative framing. For mammography screening, intention to participate has also been shown to be influenced by framing effects [95]. Hembroff et al. [96] found significant differences in knowledge based on whether numeric information was given in absolute or relative terms. In a review on risk framing, Edwards et al. [97] found that loss framing (versus gain framing) resulted in higher screening uptake and relative risk reduction (versus absolute risk reduction) in higher perceived benefit of screening. Interestingly, the base rate was neglected (changing the number of deaths had an effect irrespective of a change in actual rates [97]). Percentages seem more difficult to understand than natural frequencies [98]. Comparing two different risks poses an additional problem if they do not have the same denominator or apply to otherwise discordant groups [56]. People receiving information with absolute risks were less likely to be influenced by physician recommendations than people receiving information that reported only relative risks [99]. As a result, numeric information in absolute numbers with a common denominator (e.g., 3 out of 200 compared to 5 out of 200) should be used in DAs.

DAs may benefit from using graphical information. Research shows that graphical presentation of the numbers is beneficial [65, 85, 90]. Compared to numeric information, crowd-figure-pictograms – also called icon-arrays or pictographs – improve understanding of probability [90], accuracy of risk perception [100], and medical decision making [101]. In a previous study on lung cancer screening [102], presentation of numbers and crowd-figure-pictograms in combination resulted in higher knowledge levels than numbers alone. Different types of icons are used in crowd-figure-pictograms. Person icons are most preferred by users and lead to improved risk recall [103]. Furthermore, they invite identification between individual and icon [104]. Systematic ovals and numbers lead to accurate understanding, while random ovals (i.e., ovals that are randomly highlighted in a crow-figure-pictogram as opposed to in one block) and pie charts lead to the most errors [54]. However, it remains uncertain, whether crowd-figure-pictograms complementing numeric information items increase knowledge about mammography screening [46]. We therefore, conducted a study (German Clinical Trials Register DRKS00014736) to evaluate the effect of crowd-figure-pictograms on women's numeric knowledge about mammography screening (see *Manuscript 1* in Textbox 1). A total of 552 women were randomised to the trial arms [46]: (1) control intervention (only non-numeric information); (2) numeric intervention (non-numeric and numeric information); (3) crowd-Figure-Pictogram intervention (non-numeric and numeric information complemented by crowd-figure-pictograms using person icons). All interventions consisted of excerpts from the 2008 brochure of the Cochrane Collaboration 'Screening for breast cancer with mammography' [105] and provided information about the purpose of screening, improved survival, overdiagnosis, overtreatment, false-alarm, pain at examination and false-reassurance.

The crowd-figure-pictogram and the numeric intervention were effective compared to the control, and the crowd-figure-pictogram intervention showed added benefit compared to the numeric intervention [46]. Since this showed that crowd-figure-pictograms in combination with absolute numbers increase knowledge [46], they should be regarded in DA development.

Textbox 1. *Overview of Manuscript 1: Crowd-Figure-Pictograms Improve Women's Knowledge About Mammography Screening: Results From a Randomised Controlled Trial.*

WHAT IS ALREADY KNOWN ON THIS TOPIC Mammography screenings are often performed without women knowing about the likelihood of benefits and harms. Pictorial data have been shown to lead to better understanding compared to verbal information in explaining probability. At the time of this study, pictorial data had not been included in information materials designed for women in the target age group of mammography screening programs.

WHAT THIS MANUSCRIPT ADDS This study was the first to apply crowd-figure-pictograms to mammography screening information materials containing the outcome probabilities for women in the age group invited to population based mammography screening. Our results suggest that pictograms in combination with numeric information in absolute numbers lead to a larger knowledge increase than solitary presentation of absolute numbers. Both numeric information alone and numeric information supplemented by crowd-figure-pictograms led to significant increases in knowledge compared to the control receiving only non-numeric information.

WHY THIS MANUSCRIPT IS IMPORTANT FOR THE RESEARCH CUMULUS A DA is a combination of several improvements compared to usual care. Therefore, through testing the effectiveness of a DA, we cannot ascertain which components are effective. Accordingly, before using crowd-figure-pictograms in the DA, it was important to assess whether these have an effect on knowledge.

2.5.3. Perception of Values

Women need to be supported through clarification of the meanings of benefits and harms for themselves [18]. It needs to be clearly stated that a decision is to be made and that there is no correct course of action [3] – only a personally preferred course of action [69]. Evidence about benefits and harms of mammography screening is not so univocal as to point in one direction of behavioural advice [4]. A DA is most useful in preference sensitive decisions; nevertheless, the optimal level of detail is controversial [13]. One way to support women regarding clarification

of the meanings of benefits and harms for themselves is values clarification methods. These methods help determine the desirability of available options, e.g., through rating the importance of important possible consequences of a health intervention. Feldman-Stewart et al. [106] compared an intervention with only structured information to one additionally including values clarification methods and report that the values clarification methods decreased decision regret at a 1-year follow-up. Accordingly, values clarification methods can improve the congruence of attitude and intention and, therefore, should be used in DAs.

2.5.4. Usefulness to the Target Group

Women at whom the DA is targeted differ on many dimensions; they may have different information needs and cognitive and emotional abilities [89, 107]. These dimensions may affect the usefulness of the DA. One especially important dimension is health literacy because it is crucial for understanding information [32]. Health literacy comprises cognitive, social, and motivational skills which enable people to access, understand, and use health information [108]. As a counterpart, informed choice requires accessing, understanding, and processing health information [109]. In line with this, the National Action Plan Health Literacy in Germany advises presenting health information in a user friendly way [110]. Research [111] showed that 54.3 % of the German population had limited health literacy (i.e., had difficulty in finding, understanding, and using health information). Regarding appraisal of benefits and harms of different health care options, 43.4 % reported difficulties [111]. This is especially problematic because people with low health literacy report worse self-perceived health [112] indicating that limited health literacy may affect health outcomes. Research shows that effectively using a DA may be influenced by the user's health literacy [66]. In a systematic review of DAs, lower health literacy was associated with lower health knowledge [113]. People with lower health literacy are less likely to benefit from health education materials because they have difficulty comprehending written information making them less likely to acquire new knowledge [114]. Regarding mammography screening, lower performance on a skill-based test of health literacy was associated with lower knowledge [115]. Additionally, low health literacy was associated with low numeracy skills (hindering women to understand the likelihood of benefits and harms of mammography screening [55]), higher decisional uncertainty [116], and less willingness to be involved in decision making [117]. It is questionable whether a one-size-fits-all approach is adequate regarding different levels of health literacy of the DA-users [118]. Women with a lower level of health literacy could benefit less from a DA. People with low health literacy need more decision support since they report less motivation to engage in decision making and higher levels of decision uncertainty and regret [66]. Therefore, a DA can be especially valuable for them [118]. Three theoretical approaches for developing information materials can be applied to ensure the materials are useful for people of varying degrees of health literacy [118]: (1) tailoring so that a certain version of the information material is adapted to a person's unique

characteristics (which are derived from an initial individual assessment of influential factors [119]); (2) targeting where information material is intended for a certain subgroup [119]; (3) specific to health literacy, the universal precautions approach [120]. With this third approach, information materials are developed so people can understand them irrespective of their health literacy level [118] because it is deemed impossible to accurately identify those for whom a certain version is suitable and health literacy can be situational (e.g., depending on the person's stress level or on the health issue of interest [120]). For these reasons, a universal precautions approach can be considered most promising for the development of a DA [118].

As a specification of health literacy, eHealth literacy involves seeking and appraising information on a health issue via electronic sources and using this information [109]. It allows participation in health decisions through informing oneself through online health resources [109]. Health literacy and eHealth literacy mainly differ by the mode of health information consumption [121]. Regarding the successful use of an Internet-Based DA (see Section 2.5.5), eHealth literacy is superior to traditional health literacy in enveloping the necessary skills to benefit from this form of DA [118].

Another important dimension on which women differ is education level. Positive associations between educational level and knowledge about mammography screening have frequently been reported [11, 41, 43, 45, 83]. Looking at the dimensions of informed choice, both eHealth literacy and education were most likely to influence *knowledge* about mammography screening. Previous research indicates that knowledge is an outcome affected by both decision aids [13] and eHealth literacy [113, 122]. For the other dimensions of informed choice previous research has not shown consistent effects of DAs [13].

2.5.5. Accessibility

The DA needs to be accessible to women invited to the MSP. An Internet-Based DA (i.e., a DA that was specifically designed and tested for use on the Internet) has the advantages of being highly accessible, easy to update, and very cost-effective. Additionally, it is available at the appropriate time in the decision making process [68]. Furthermore, an interactive DA is only realisable on the Internet and not on paper. Internet-Based DAs are an important class of DAs and there is increased searching on the Internet related to medical decisions [68]. Accordingly, one IPDAS dimension is the delivery of patient DAs on the Internet [68] and a DA can benefit from being Internet-Based. As a conclusion for DA development, content, presentation, and clarification of values have to be regarded, and adequacy for the target group's health literacy and education level as well as accessibility have to be ensured. Furthermore, the effectiveness of the DA has to be established.

3. Aims and Objectives

This project was the first to develop and systematically evaluate an interactive Internet-Based DA for the MSP. As primary objective, we evaluated whether the DA increased the rate of informed choices [18, 69]. As secondary objectives, we evaluated whether the DA [18, 69]

1. increased knowledge[1] about the MSP,
2. changed attitude on the MSP,
3. changed the proportion of women intending to participate in the MSP,
4. changed the proportion of women participating in the MSP,
5. reduced decisional conflict,
6. reduced decision regret,
7. was moderated in its effect on knowledge by eHealth literacy, and
8. was moderated in its effect on knowledge by education.

4. Methods

4.1. Development of the Decision Aid

Based on the criteria of the IPDAS Collaboration, we developed an Internet-Based DA for women invited to the MSP for the first time [69]. At its core, the DA aimed to enable a structured decision-making process [18]. The information from the official brochure accompanying the MSP invitation at the time of our study [82] was used as an informational basis for the information part of our DA so that the DA would provide more comprehensive information but not conflicting information. The structure of the DA was based on that of Mathieu et al. [70]. In line with the IPDAS criteria [123], the DA presented the options of choice (participation or non-participation in the MSP) in a decision-relevant context [18, 69].

We intended our DA to comply with the universal precautions approach: The DA aimed to be understandable for all women aged 50 irrespective of their eHealth literacy level or education level [118]. In the information part of the DA, advantages and disadvantages of the MSP were described in absolute numbers illustrated by crowd-figure-pictograms [69]. The interactive part of the DA summarised the main points of the information part and encouraged engagement with the information [69]. The probabilities of a positive and negative screening result were presented [18]. We explained overdiagnosis, overtreatment, and the procedure following a positive result

[1] The secondary outcomes listed under points 1 to 4 are dimensions of the primary outcome informed choice.

[18]. Positive and negative information were presented in a balanced way according to current evidence [18].

The initial version of the DA was evaluated in a qualitative pre-test with (1) women of the target group and (2) experts from the National Network Women and Health [18]. This qualitative pre-test indicated that information on the likelihood of all cause mortality should be included in the DA [69]. This was followed by a quantitative pre-test of the DA to which 300 women were invited; 53 women participated [18].

In the following, both the brochure (usual care) and the DA are described to allow comparison (for a more detailed description, see Table 1 in *Manuscript 5* in the Appendix): The brochure was a 12-page paper-based booklet sent with the invitation to the MSP [69]. Contrastingly, the DA was developed as an Internet-Based tool consisting of an information part and interactive part [18, 69, 118]. It comprised crowd-figure-pictograms, a graphical summary of the values clarification method, and a downloadable PDF including the personal responses [69]. Both the brochure and the DA presented the numbers of negative screening results, positive screening results, breast cancer diagnoses, interval cancers, and overdiagnoses [69]. While the brochure and DA similarly presented the number of breast cancer deaths with mammography screening, the brochure reported only the number of *additional* deaths without mammography screening whereas the DA reported the total number of breast cancer deaths without mammography screening. Only the DA comprised numeric information on all-cause mortality with and without mammography screening [69]. Regarding the presentation of quantitative information, the brochure used absolute numbers presented in text [69]. The DA presented quantitative information using absolute numbers and crowd-figure-pictograms [69]. The three crowd-figure-pictograms in the DA each consisted of 200 female pictograms (200 women with biannual mammography screening over 20 years) and depicted (1) breast cancer mortality with mammography screening, (2) breast cancer mortality without mammography screening, and (3) false-positives, breast cancer diagnoses, and interval cancers with mammography screening [69]. Thus, the chance of each outcome was expressed as event rate based on the same population of 200 women screened every 2 years for 20 years [69]. Through the use of crowd-figure-pictograms, the positive and negative frames (e.g., women dying of breast cancer versus women not dying of breast cancer) of outcomes were simultaneously depicted [18]. Uncertainty in the evidence (i.e., that the presented number are best estimates and that they may have to be modified as new evidence becomes available) was noted in the introduction. In contrast to the brochure, the DA comprised a values clarification method [69] based on that of Mathieu et al. [70]. This allowed women to (1) evaluate the information items as in favour of, neutral or against mammography screening, (2) rate the importance of each information item, and (3) make a decision about participation in the MSP. At the end, a summary of the personal responses was available [69]. Through this approach,

the importance of a personal value-based assessment of information was highlighted [18]. After the end of the below described evaluation of our DA, it was made available to the public on the BARMER website (https://www.barmer.de/gesundheit/praevention/krebspraevention/krebsfrueherkennung/mammographie-13876) and was registered in the Decision Aid Library Inventory (https://decisionaid.ohri.ca/AZsumm.php?ID=1673) [69].

4.2. Evaluation of the Decision Aid

4.2.1. Design

Manuscript 2 (see Textbox 2) describes the methodology of the evaluation of the above described DA in detail. In this RCT (German Clinical Trials Register DRKS00005176 [18, 69]), the participating women were randomised to receive either (1) the DA (intervention group) and usual care or (2) only usual care (control group). At the time our study was conducted, usual care for women in the MSP targeted age group involved being sent an invitation to the programme accompanied by an information brochure (see [82]). We conducted a baseline, a post-intervention, and a 3-month follow-up assessment [18, 69].

Textbox 2. *Overview of Manuscript 2: Does a Decision Aid Improve Informed Choice in Mammography Screening? Study Protocol for a Randomized Controlled Trial.*

WHAT IS ALREADY KNOWN ON THIS TOPIC Mammography screening choices should be informed choices. Unfortunately, this is often not the case. DAs can support women in making informed choices about mammography screening. Any DA should be systematically developed and evaluated to ensure its effectiveness.

WHAT THIS MANUSCRIPT ADDS This Manuscript describes the development of the DA and the study protocol for the RCT with a 3-month follow-up to assess the effectiveness of this DA. At the time of this study, no RCT-evaluated DA for the MSP existed. This DA was the first developed for women aged 50 invited to the MSP conforming to the quality criteria of the IPDAS Collaboration.

WHY THIS MANUSCRIPT IS IMPORTANT FOR THE RESEARCH CUMULUS This Manuscript details the development of the DA and the study protocol for its evaluation. Evaluating the DA was only possible with a rigorous research design. Its methodology needed to be presented in a transparent manner enabling future replication.

4.2.2. Procedure

Three weeks prior to the estimated arrival of the MSP invitation, we mailed the letter of invitation to the study followed by a reminder/thank-you postcard to increase the response rate [18].

Women who had given informed consent were then e-mailed the link to the baseline questionnaire and randomised to the intervention or control group by the researchers through an allocation sequence generated by a random number generator [69]. Two weeks after the baseline assessment, they received a link to either the DA and second assessment or only the second assessment [18]. Three months after the post-intervention assessment, we assumed the screening appointment to have passed and women received the link to the follow-up assessment [18].

4.2.3. Data Management

Data protection was of importance as mammography screening behaviour and attitudes are sensitive topics. Therefore, data from all measurement points were linked through self-generated codes [69, 118]. Such codes consist of elements only known to the participant to ensure anonymity [124]. The downside of self-generated codes is their flawed linkage performance [124]: Participants may provide different values as code components or more than one participant may provide the same code components [124]. More specific to this study was a third problem: Participating women started the survey several times, each time creating a duplicate of the code. The main difficulty in linking self-generated codes is that creation of false-negative cases has to be balanced against false-positive cases. To deal with this problem, we matched codes with the Levenshtein string distance function (an algorithm measuring the difference between two string variables [125]) as suggested by Schnell et al. [124]. The program Merge Toolbox was used for linking self generated codes [124].

4.2.4. Outcomes

At the time of this project, no instrument to assess informed choice in the context of the MSP existed [35]. As described in *Manuscript 3* (see Textbox 3), we developed and psychometrically evaluated an instrument, called 'Informed Choice in Mammography Screening Questionnaire (IMQ)' [35] in the context of the project 'Informed Choice of German and Turkish Women for Participation in the Mammography Screening Programme (InEMa)' which aimed to assess the level of informed choices in women invited to the MSP for the first time [12, 126]. The IMQ [35] was to assess informed choice equally well in both autochthonous and Turkish women and has been developed after consideration of (1) literature on existing informed choice instruments, (2) the results of qualitative interviews on decision making in the MSP with German and Turkish women, and (3) a qualitative study with Turkish women on factors influencing uptake of the MSP [127]. The literature search for existing instruments on informed choice in mammography screening produced mostly instruments measuring knowledge [35]. Therefore, we conducted a subsequent literature search for instruments assessing informed choice in other health contexts [35].

The qualitative interviews determined what informed choice meant for women in the con-

text of (non-)participation in the MSP and how the decision-making process evolved [35]. Four autochthonous and two Turkish women aged 50 to 55 were interviewed [35]. The interview guidelines were developed according to Helfferich [128]. Content analysis [129] showed that women made the decision for or against participation after some time had passed, in which they sought advice from physicians and friends [35]. MSP participation was termed the 'reasonable' action [35]. Main barriers were that women did not wish to have another appointment and having to wait between the mammogram and receiving the result. Women remarked that overtreatment was hard to imagine. Informedness had a low priority because the women were not interested in the topic and did not perceive informedness as helpful for the decision [35].

Based on the Reasoned Action Approach [57] and the model of informed choice [6], we assessed three scales (attitude, norms, and barriers), one index (knowledge) and intention to participate [35]. Thus, the IMQ assessed the three dimensions necessary to form informed choice as well as mapping the decision within the predictive model of the Reasoned Action Approach [35]. Barriers and norms were not evaluated as outcomes of the main project 'Development and Testing of a Decision Aid for Mammography Screening, EnTeMa' and are therefore not described further.

To assess its psychometric properties, the German version of the IMQ was sent to 17,349 women aged 50 in Westphalia-Lippe, North-Rhine Westphalia, Germany [35]. A total of 5,847 women (33.7 %) responded, 5,293 German questionnaires were available to evaluate the psychometric properties [35]. Both the attitude scale and the knowledge index showed to be suitable measures. Correlation patterns supported validity.

Textbox 3. *Overview of Manuscript 3: Development of the Informed Choice in Mammography Screening Questionnaire (IMQ): Factor Structure, Reliability, and Validity.*

WHAT IS ALREADY KNOWN ON THIS TOPIC Informed choice is important – both from an ethical and a practical perspective. To assess the level to which choices regarding mammography screening are informed, an adequate measurement instrument is needed. At the time of this study, no adequate instrument for assessing informed choice in the MSP had been available.

WHAT THIS MANUSCRIPT ADDS This study describes (1) the development of the IMQ and (2) evidence for the factor structure, reliability and validity of its different components. The attitude scale was shown to have a one-factor structure and good reliability. The knowledge index retained 6 out of 7 original items after item response theory analysis and was shown to have a 2-parameter-logistic-structure. Correlation patterns of the outcomes supported their convergent and divergent validity.

WHY THIS MANUSCRIPT IS IMPORTANT FOR THE RESEARCH CUMULUS This manuscript was important because it demonstrated that the psychometric properties of the attitude scale and knowledge index were suitable, so that these can be used in future research (e.g., the study on the effectiveness of our DA).

Modifications were made to the IMQ to make it suitable for evaluating an intervention and to be used online. All outcomes assessed in the EnTeMa project (including the just described attitude scale and knowledge index) are described in the following paragraphs (for a detailed description of all outcomes, see *Manuscript 2* in the Appendix).

Informed choice was assessed through the dimensions of the classification framework of Marteau et al. [6] covering the following dichotomously coded outcomes [18, 35, 69]: (1) knowledge (sufficient/insufficient), (2) attitude (positive/negative), and (3) intention/uptake (depending on the measurement point; yes/no). Since there are no agreed criteria for defining sufficient knowledge [59], the midpoint of the knowledge index was used similar to previous studies [10, 11, 59, 130]. Attitude was dichotomised using the neutral mid-point of the bipolar scale (≥ 0 was classified as positive attitude [35]) similar to van Agt et al. [11].

Acceptability of the DA was assessed with one item assessing whether the tailored graphic in the DA was balanced and four items assessing acceptability of the DA regarding length, amount of information, one-sidedness, and helpfulness in decision making [18].

Knowledge was assessed using seven multiple choice items on (1) target group of the MSP, (2) number of women receiving a positive result, (3) number of false-positives, (4) existence of false-negatives, (5) breast cancer diagnoses (MSP versus no MSP), (6) breast cancer deaths (MSP versus no MSP), and (7) existence of overtreatment [18, 69]. These were based on the knowledge questions of Mathieu et al. [70] and on our previous study on knowledge increase through use of pictograms [46]. In the InEMa study, the development and psychometric properties of the knowledge index were evaluated (see *Manuscript 3* for details). We tested the unidimensionality assumption of item response theory (IRT) by fitting a 2-parameter-logistic IRT model [35]. Item 6 was excluded following the evaluation of discrimination and difficulty parameters; the remaining six items indicated an adequate model fit and sufficient unidimensionality [35]. Subsequently, we specified a 1-parameter-logistic model and compared this to the 2-parameter model to establish whether item discrimination was equal between items [35]. The 1-parameter-logistic model fitted worse than the 2-parameter-logistic model [35]. In the EnTeMa study (see *Manuscript 5*), a 2-parameter-logistic item factor analysis confirmed that Item 6 was problematic [69] and it was accordingly excluded from analysis.

Attitude was assessed with four items developed by Marteau et al. [6] and in concordance with the Reasoned Action Approach of Fishbein and Ajzen [57]. Four semantic differentials (important/unimportant; a good thing/a bad thing; advantageous/disadvantageous; pleasant/

unpleasant) assessed attitude on MSP participation [18, 35]. All items had acceptable indices (difficulty, variance, and discrimination; see *Manuscript 3*) and the scale possessed an acceptable factor structure and internal consistency [35].

Intention was measured using one item regarding intention to participate in the MSP in the next 3 months [18, 69]. For analysis, intention was dichotomised as 'participation in the MSP' and 'no participation in the MSP' and undecided women were excluded [69]. In addition, women who reported at post-intervention as wanting to participate in opportunistic screening were excluded [69] because in Germany in this age group, only women with either a high risk profile or suspected breast cancer should receive opportunistic screening [35].

Uptake was assessed at a 3-month follow-up with one item regarding mammography screening participation in the last 3 months [18, 35]. Uptake was dichotomised as 'participation in the MSP' and 'no participation in the MSP' excluding women who had participated in opportunistic screening [69].

Decisional conflict was measured using the 4-item SURE-test (Sure of myself; Understand information; Risk-benefit ratio; Encouragement [131]). Since no German translation of this test was available, the test was translated as part of this project [18].

Decision regret was measured using the 5-item Decision Regret Scale [132]. Since no German translation of this scale was available, the scale was translated as part of this project [18].

Decision stage was assessed with the answer options 'not thought about it', 'contemplating it', 'close to deciding', and 'choice already made' [133].

eHealth literacy was assessed using the eHealth Literacy Scale (eHEALS [134]). The eHEALS is the most frequently used measurement instrument to assess eHealth literacy [135]. It measures the perceived ability to find, evaluate and use health related information gained in electronic environments [134] and comprises eight items covering (1) knowing how to find information online, (2) knowing how to use the Internet to answer questions, (3) knowing what health resources are available, (4) knowing where to find health resources, (5) knowing how to use this health information, (6) having the skills to evaluate health resources, (7) ability to discriminate between high and low quality resources, and (8) confidence to use information to make health decisions. Its German translation was validated and its factorial structure was elaborated (see *Manuscript 4* in Textbox 4) as part of a cross-sectional survey of 12th grade students on health competence [136, 137]. According to the findings of the structural model of health competence of Soellner et al. [138] and based on the content of the items, a 2-factor model of the eHEALS with the two subscales information-seeking (Items 1–5 and 8) and information-appraisal (Items 6 and 7) appeared more plausible than the 1-factor model proposed by Norman & Skinner [134]. This was confirmed by the 2-factor model showing a better model fit [137]. The reliability did not deteriorate through splitting the scale, and construct validity of the two concepts was supported

by correlation patterns with different health competence constructs [137]. For using the DA, we assumed it to be most important to have the ability to use information for health decisions [118]. In the EnTeMa study, we, therefore, decided to additionally test a 3-factor model in which the information-seeking subscale was split into two 3-item subscales [118]: information-seeking (Items 1, 3, and 4) and information-use (Items 2, 5, and 8).

Textbox 4. *Overview of Manuscript 4: The Concept of eHealth Literacy and Its Measurement – German Translation of the eHEALS.*

WHAT IS ALREADY KNOWN ON THIS TOPIC eHealth literacy is an important skill for people in navigating the health care system and in using health information to their benefit. Many conceptual approaches and thus instruments to assess eHealth literacy exist. The eHEALS is the most widely used measure of eHealth literacy but no German translation existed at the time of this study and there remains controversy surrounding its factorial structure.

WHAT THIS MANUSCRIPT ADDS This study translated the eHEALS into German and compared the 1-factor model based on Norman and Skinner's analyses with the 2-factor model of the eHEALS comprising the subscales information-seeking and information-appraisal through a confirmatory factor analysis. The 2-factor model showed a better model fit.

WHY THIS MANUSCRIPT IS IMPORTANT FOR THE RESEARCH CUMULUS eHealth literacy was an important outcome to assess in the evaluation of the DA since research suggests that effectively using a DA may depend on the users' eHealth literacy level. To assess eHealth literacy, we needed an instrument in German, the psychometric properties of which had been evaluated. This Manuscript provided a German translation and results on the psychometric properties of this translation.

Education was assessed using the German degree options of 'Hauptschulabschluss' (9 years), 'Realschulabschluss' (10 years), 'Polytechnische Oberschule' (10 years), 'Fachhochschulreife' (11 to 12 years), 'Abitur' (12 to 13 years), other, and no school degree [118]. For the moderation analysis, we dichotomised these different degrees in 'up to 10 years of education' and 'more than 10 years of education' [118].

4.2.5. Participants

A representative sample of 7,400 women was randomly drawn from registration office data of the district of Westphalia-Lippe, North Rhine-Westphalia, Germany [18, 69, 118]. Only women

aged 50 were eligible for this trial because they are invited to the MSP for the first time [18, 69]. The sample size was calculated using G*Power for the primary outcome informed choice. Based on the study of Mathieu et al. [70], we determined a difference in the proportion of informed choices of 7 percentage points as the minimum clinically important difference for the power calculation and, thus, a sample of 740 women as sufficient [18]. Allowing for an estimated response rate of 15 % (we estimated our response rate to be half of the 33.7 % of the InEMa study [35], since we used online questionnaires instead of paper-and-pencil questionnaires) and early drop-out of one-third of initial participants, we needed to invite 7,400 women to take part in the study [18]. Women with a potential Turkish migration background (according to a name algorithm [139]) had already been assigned to the InEMa study [126] and accordingly, our sample comprised only women without Turkish migration background [69]. Women who had ever been diagnosed with breast cancer were excluded [18].

4.2.6. Data Analysis

Data were analysed with SPSS versions 23 and 24 (IBM, Corp., Armonk, NY) and MPlus versions 7 and 8 (Muthén & Muthén, Los Angeles, CA). Possible baseline differences between trial arms were statistically tested with an α of .15 [69]. The effect of the DA on the primary and secondary outcomes was analysed [69]. For the primary outcome informed choice, the effect was analysed using cross-sectional χ^2-tests for all measurement points. Secondary outcomes with a single-indictor were analysed according to their measurement level either with χ^2-tests (intention and uptake) or Mann-Whitney-U-tests (decision stage).

All secondary outcomes with several indicators were analysed with latent structural equation models which allowed (1) to account for measurement error, (2) to test measurement invariance, and (3) to apply full information maximum likelihood estimation enabling us to include individuals with missing values in the analysis [69]. Since measurement invariance is a necessary condition to conduct and interpret analyses on longitudinal multigroup data [140], measurement invariance levels were tested across time and group prior to the analyses of intervention effects [69]. Partial invariance (i.e., invariance of the majority of indicators, with some parameters being freely estimated [140]) was tested if full measurement invariance was not tenable. Missing data patterns likely to be found in the current study were a monotone missing data pattern, where participants drop out of the study and a general (i.e., non-monotone) missing data pattern. Maximum likelihood estimation is one of the two state-of-the-art techniques for handling missing data [141]. It calculates the population parameters that have the highest probability of having produced the data included in the analysis model [142]. In full information maximum likelihood estimation, model parameters are estimated through a 2-step iterative procedure (the expectation-maximisation algorithm) searching for maximum likelihood parameter estimates. These maximum likelihood estimates then represent the parameter values for which the data are

most likely to be observed [143].

To test the intervention effect, latent models (see Figure 2 in *Manuscript 5* in the Appendix) with structural models comprising a first order autoregressive effect of baseline on post-intervention and a second order autoregressive effect of baseline on follow-up were specified. Importantly, group was included as a predictor of latent outcomes at post-intervention and follow-up [69]. To determine the measurement models, two types of latent analyses were used for the secondary outcomes [69]. (1) We conducted confirmatory factor analysis (CFA) for the numeric outcomes forming a continuous latent factor (i.e., attitude and decision regret). (2) We conducted 2-parameter-logistic item factor analysis for categorical outcomes forming a continuous latent factor (i.e., decisional conflict and knowledge). The structural model was, as described above, similar for both.

To test the moderation effect of eHealth literacy, we first tested the factor structure of the eHEALS by comparing the 2-factor model [137] we found in previous research (see *Manuscript 4*) to the originally proposed 1-factor model [134]. Then we compared our proposed 3-factor-model with the better-fitting-model of the two [118]. Finally, we specified the measurement model of eHealth literacy according to the superior factor model and tested whether eHealth literacy moderated the effect of the DA on knowledge [118]. In concordance with our previous analyses of knowledge [69], we included a first order autoregressive effect of knowledge at baseline on knowledge at post-intervention in this model. Thus, the structural model estimated the effects of (1) knowledge at baseline, (2) the DA, (3) the components of the eHEALS, and (4) their interactions with the DA on knowledge at post-intervention [118]. Subsequently, we included education and its interaction with the DA in the model.

5. Results

5.1. Participation and Completion Rates

Of 7,400 women invited, 1,206 participated (response rate of 16.3 % [69, 118]). Women who ever had breast cancer, did not respond to this question, or reported at post-intervention – regardless of whether they had participated in the MSP – that the date of the MSP appointment had passed were excluded. Overall, we included the data of 913 women in the analysis [69, 118].

5.2. Baseline and Control Group Characteristics

The majority of women had a school education of up to 10 years followed closely by slightly less than half of the women having had a school education of more than 10 years [118]. Nearly all reported German as their main language [69]. 90 % had a statutory health insurance [69]. Over 80 % spent more than one hour per week on the Internet searching for information [118]. The Internet as an information source for health topics was rated as important by nearly 60 % [118].

At baseline, nearly 60 % had already received the invitation to the MSP [69, 118]. However, this was not an exclusion criterion since the invitation was likely to have arrived by post-intervention and the information materials of the MSP are available online. More than 60 % of the participating women had had a mammogram in the past; of those, more than half reported that the mammogram had been conducted for screening purposes (since women had just entered the screening age group of the MSP, these previous mammograms refer to mammograms performed outside of the MSP [69]). At baseline, all described background variables did not differ between the two groups [69].

For the control group, the following results can be reported. The proportion of women making an informed choice was constant at about 30 % over all three measurement points [69]. At baseline and post-intervention, about 30 % and at follow-up, about 40 % of women had adequate knowledge [69]. More than 80 % of women at all measurement points had a very positive attitude towards participation in the MSP [69]. At baseline and post-intervention, about 90 % of women intended to participate in the MSP within the next 3 months [69]. At follow-up, about two-thirds of women had participated in the MSP and few women experienced decision regret [69]. At baseline, 68 % indicated they had already made a decision [69]. This percentage increased to 77 % at post-intervention [69]. At baseline, all described outcome variables did not differ between the two groups [69].

5.3. Acceptability of the Decision Aid

More than 75 % of women regarded the length and the amount of information of the DA as appropriate. More than 80 % considered the directionality of the DA as balanced and, therefore, neither directed at participation nor at non-participation. The DA had facilitated the decision only for slightly more than 20 % of participating women. The majority said that the DA did not affect the ease of decision making (see Table 1 for the results not published previously). For most women, the result of their personal DA was 'in favour of participation' (72.9 %). For few women the result was 'against participation' (17.3 %) or 'equally for both options' (9.7 %).

5.4. Effectiveness of the Decision Aid

Fulfilling a prerequisite of latent outcomes for testing the effectiveness of the DA over measurement points and groups, the confirmatory factor models showed partially strong measurement invariance was tenable for attitude and strong measurement invariance for decision regret [69]. The 2-parameter-logistic item factor models showed partially strong measurement invariance for knowledge and decisional conflict [69].

The proportion of women making an informed choice was significantly higher in the DA group at both post-intervention (61.5 % versus 28.9 %) and follow-up (39.8 % versus 30.3 % [69]; see *Manuscript 5* in Textbox 5). Similarly, women in the DA group had significantly higher knowledge

Table 1

Acceptability of the decision aid

Item	Response	*n* (%)
The decision aid was...	too long	49 (15.3)
	too short	23 (7.2)
	just right	248 (77.5)
The amount of information was...	too large	29 (9.1)
	too small	46 (14.5)
	just right	243 (76.4)
The decision aid was...	one-sided towards participation	37 (11.6)
	one-sided towards non-participation	20 (6.3)
	balanced	262 (82.1)
The decision aid made my decision...	easier	70 (21.6)
	more difficult	19 (5.9)
	neither nor	235 (72.5)

levels and significantly lower decisional conflict than women in the control group compared to baseline at both post-intervention and follow-up [69]. At post-intervention, women in the DA and control group did not differ significantly in their attitude compared to baseline whereas at follow-up, women in the DA group had a significantly more negative attitude [69]. At post-intervention, the proportion of women who did not want to participate in the MSP was significantly higher in the DA group than in the control group [69], whereas at follow-up, there were no significant differences in uptake between the groups [69]. Decision stage at post-intervention and decision regret at follow-up did not differ significantly between groups [69].

Textbox 5. *Overview of Manuscript 5: Does a Decision Aid Improve Informed Choice in Mammography Screening? Results From a Randomised Controlled Trial.*

WHAT IS ALREADY KNOWN ON THIS TOPIC Few decisions about participation in the MSP are informed choices. DAs can increase the proportion of informed choices. Information materials about the MSP are insufficiently evaluated and do not comply with quality criteria to a desirable extent. At the time of this study, no RCT-evaluated DA existed for the MSP.

WHAT THIS MANUSCRIPT ADDS We developed the first DA for the MSP that fulfilled the quality criteria of the IPDAS Collaboration. This DA increased informed choice and knowledge and lowered decisional conflict. While it had no effect on uptake at follow-up,

it did decrease the intention to attend mammography screening at post-intervention. The DA led to a more negative attitude towards mammography screening at follow-up but did not influence decision regret or decision stage.

WHY THIS MANUSCRIPT IS IMPORTANT FOR THE RESEARCH CUMULUS This manuscript describes the first systematic evaluation of a DA for the MSP. The DA showed to be an effective tool to increase informed choices. Before making the DA available to the public and investigating effects further, an effectiveness analysis was essential.

5.5. Moderators of the Effect of the Decision Aid

The 3-factor model of the eHEALS had the best model fit, followed by the 2-factor model and the 1-factor model (see *Manuscript 6* in Textbox 6). To test the moderation, an interaction model was specified. In this model, knowledge at baseline predicted knowledge at post-intervention (see Figure 2 in *Manuscript 6* in the Appendix). The DA increased knowledge at post-intervention [118]. None of the three factors of the eHEALS (information-seeking, information-appraisal, information-use) had an effect on knowledge at post-intervention [118]. The DA did not interact with information-seeking, information-appraisal, or information-use [118]. Thus, the hypothesised moderation effect of information-use on the effect of the DA was not confirmed [118]. Information-seeking, information-appraisal, and information-use showed high positive covariances with each other [118]. With baseline knowledge, all three showed negative covariances [118]. Thus, people with higher levels of information-seeking, -appraisal, and -use had lower levels of baseline knowledge and vice versa [118].

In a subsequent model, we included education (up to 10 years versus more than 10 years) and its interaction with the DA (see Figure 3 in *Manuscript 6* in the Appendix). Both education and its interaction with the DA did not predict knowledge at post-intervention [118]. All other results were similar to the previously described model [118]. Education was not associated with any of the baseline outcomes in the model [118].

Textbox 6. *Overview of Manuscript 6: Do Women With High eHealth Literacy Profit More From a Decision Aid on Mammography Screening? Testing the Moderation Effect of the eHEALS in a Randomized Controlled Trial.*

WHAT IS ALREADY KNOWN ON THIS TOPIC The DA on mammography screening developed in this research project increases knowledge compared to usual care. Other research indicates that effectively using a DA may be moderated by the user's eHealth literacy. The eHEALS is the most widely used measurement instrument to assess eHealth

literacy but controversy remains surrounding its factor structure – something that needs to be determined before testing any moderation effects on the DA.

WHAT THIS MANUSCRIPT ADDS This study analysed whether the DA is more effective in women with higher eHealth literacy (i.e., whether the effect of the DA on knowledge is moderated by eHealth literacy). Our data indicate that the eHEALS has a 3-factor structure comprising information-seeking, information-appraisal, and information-use. None of these moderated the effect of the DA on knowledge nor were there any main effects on knowledge. Similarly, education level neither moderated the effect of the DA nor showed a main effect on knowledge.

WHY THIS MANUSCRIPT IS IMPORTANT FOR THE RESEARCH CUMULUS It is important to know how effective the DA is in different population groups. Previous research indicated that it is likely that the DA could be less effective in women with low eHealth literacy. Reassuringly, the DA developed in this project increased knowledge irrespective of level of eHealth literacy or education. We can thus assume that the DA is a comprehensible information tool that can be used successfully by women of varying eHealth literacy and education levels.

6. Discussion

6.1. Synopsis of the Main Results

This was the first RCT to evaluate the effect of a DA for the MSP [69]developed according to the IPDAS criteria [61]. Regarding development of the DA, we were successful in fulfilling the following three points suggested by Gummersbach & Abholz [85] as shortcomings of usual care: All statistics were presented in absolute numbers, numbers were presented graphically, and the lack of effect of the MSP on overall mortality was mentioned. Regarding effectiveness, the DA increased the proportion of informed choices, increased knowledge, and decreased decisional conflict [69]. Intention to participate was lower following the DA [69]. Decision regret, decision stage and uptake were not affected by the DA [69]. Attitude was not affected at post-intervention but was less positive at follow-up [69]. Regarding a moderation of eHealth literacy or education on the effect of the DA on knowledge, we found neither such moderation effects nor main effects of eHealth literacy or education [118].

6.2. Integration in Previous Research

6.2.1. Baseline and Control Group Characteristics

Most choices in the control group were uninformed irrespective of measurement point [69], confirming previous research about informed choices of women invited to the MSP for the first time

from the InEMa study [12]. At baseline, less than one-third of women had adequate knowledge [69]. This proportion was higher in the InEMa study where 46 % had sufficient knowledge – but it has to be noted that the calculation differed because the weighted (instead of the unweighted) knowledge index was dichotomised [144]. In previous Australian research, over 70 % responded correctly to the knowledge items at baseline [145]. In a cross-sectional survey in the Netherlands assessing only conceptual knowledge, 95 % of women achieved sufficient knowledge [11]. These different proportions may in part be explained by differences between mammography screening programmes as well as in the accompanying information materials in different countries [69]. Additionally, it is questionable to what degree the knowledge measures were comparable. At baseline, post-intervention, and follow-up, women in both groups had a very positive attitude regarding MSP participation [69]. This is in line with previous research reporting a positive attitude for most women [11, 145]. Albert et al. [44] and Berens et al. [12] similarly reported a mainly positive attitude towards the MSP for women in Germany.

Irrespective of group, at baseline and post-intervention, the majority of women intended to participate in the MSP within the next 3 months [69], which is in line with previous research [12]. At follow-up, 62 % had participated in the MSP in both groups [69]. In 2014 (the year of our data collection), the uptake rate in the MSP was lower with 54 % [146]. In an earlier survey, Albert et al. [44] reported an uptake rate of 66 %. Interestingly, the proportion of women at follow-up who had not participated in the MSP was significantly higher than the proportion of women at post-intervention who did not intend to participate irrespective of intervention group [69]. This may reflect three different points. (1) Women changed their mind. (2) Women either received the invitation to the MSP so late that the appointment at our 3-month follow-up had not yet passed or they postponed the appointment (i.e., these women participated but not in the 3-month period we enquired). (3) Social desirability influenced intention responses (since early detection is seen as positive in general by society, intention to not participate may not be reported) whereas retrospective uptake responses may not have been biased as strongly by social desirability as attendance is more straightforward to report [69]. At baseline, the majority of women reported already having made a decision [69] similar to a previous RCT [145].

6.2.2. Effects of the Decision Aid

Acceptability of the DA. Most women regarded (1) the length and the amount of information of the DA as appropriate, and (2) the directionality of the DA as balanced between participation and non-participation. The result of their personal DA was in favour of MSP participation for the majority of women. Interestingly, only one fifth of participating women reported that the DA had facilitated the decision for them (the majority reported the DA did not affect ease of decision-making). Contrasting results from a pilot study on a DA for Australian women facing their first choice on mammography screening participation report most women considered the DA

to be helpful [147]. Similarly, Mathieu et al. [70] reported most participants found the DA for 40-year-old women helpful. Schonberg et al. [148] reported 93 % found the DA for women aged 75 and older helpful. A possible explanation for why this was only the case for few women in our study could be that the decision process was difficult and that more information did not make it easier. This may have occurred when when a tendency towards participation or non-participation had been formed previously that was then challenged in light of the new information. This is also reflected in the results regarding decisional conflict described below.

Informed choice. At both post-intervention and follow-up, our DA led to more informed choices than usual care [69]. Previous research on the effect of a DA on informed choice in mammography screening shows heterogeneous results. A DA for women aged 70 resulted in an increase in informed choices [10], while a DA for women aged 40 did not affect the proportion of women making an informed choice [70].

Knowledge. Similar to previous research on mammography screening for women aged 40 and women aged 70 [10, 70], our DA increased knowledge about mammography screening compared to usual care at both post-intervention and a 3-month follow-up [69]. The Cochrane review concluded that DAs irrespective of health topic lead to higher knowledge than usual care [13]. Nevertheless, comparing different knowledge measures should only be conducted with caution because knowledge instruments assess different aspects of knowledge, have different difficulties, and use different answer formats [35].

Attitude. Post-intervention, there were no differences in attitude between groups [69]. Similar to our results at post-intervention, Mathieu et al. [70] reported no difference in attitude. In contrast, at follow-up, women in our DA group had a more negative attitude compared to the control group [69]. Similar to our results at follow-up, a RCT reported fewer women with a positive attitude in the group receiving a DA with information on overdetection (which our DA also included) than women in the group receiving a DA without such information [145]. Our DA may have influenced women to be less positive about the MSP through increasing their knowledge and thus leading to more realistic expectations about the screening [69]. However, it remains unclear why this effect would only show at follow-up and not at post-intervention [69]. It is possible, information on mammography screening needs to ease down for some time before its effect on attitude becomes visible. New information will have either a positive, no, or a negative effect on attitude [69] depending on whether the screening offered accords with the benefits and harms that formed the initial attitude. This may at least partly explain the heterogenous research context.

Intention and uptake. Post-intervention, intention to participate in the MSP was lower in the DA group [69]. The uptake rate at follow-up was unaffected by our DA [69]. Results from previous

research are mixed both for intention and uptake. Studies reported either no effect of a DA on intention [149, 150] or a lower intention [70, 145, 148]. Similarly for uptake, research showed either no effect of a DA [10] or a lower uptake in the DA group [130]. According to the Cochrane review on DAs, a value congruent choice was more likely if the DA comprised a values clarification method [13]. Nevertheless, DAs do not have any clear effect on intention per se [13]. Similar to attitude, depending on the intervention offered and the predominant opinion on the risk-benefit ratio in the population, more information may have a positive, no, or a negative effect [69].

Decisional conflict. At both post-intervention and follow-up, women in the DA group had lower decisional conflict than women in the control group [69]. Similarly, the Cochrane review reported an overall reduction in decisional conflict after use of a DA [13]. While two RCTs on mammography screening reported no effect of a DA on decisional conflict [10, 148], another RCT reported lower decisional conflict after exposure to a DA [145] as did a pre-post study [150]. Many women may already have decided whether they wanted to attend mammography screening before receiving the DA similar to a qualitative study on a DA for hormone replacement therapy by Müller et al. [151]. In turn, the DA may then cause more decisional conflict in cases where initially formed personal preference and scientific evidence provided by the DA are incongruent [151]. In line with these results, DAs are evaluated most positively by women who merely verify their previous decision with the DA [151]. Another important point is that it remains uncertain whether high decisional conflict is a positive or a negative outcome [130] since decisional conflict could also be seen as an indicator of an active deliberation process [152].

Decision regret. Decision regret was not affected by the DA [69]. This is in line with the Cochrane review on DAs that reported only 7 of 105 studies (none on mammography screening) to assess decision regret; none of these found statistically significant differences [13].

Decision stage. Decision stage at both post-intervention and follow-up was not affected by the DA [69]. Contrastingly, Mathieu et al. [70] reported that the DA increased the proportion of women who had made a choice. Our DA may only have been relevant for women who had not yet formed a decision and, thus, their decision stage would not have been expected to alter since more than two-thirds had already made the decision at baseline leaving no room for decision process progression [69].

Moderation effect of the eHEALS. eHealth literacy did not moderate the effect of the DA on knowledge [118]. Thus, our DA increased knowledge irrespective of the level of eHealth literacy women had [118]. To our knowledge, no other studies assessing the interaction of a DA and eHealth literacy on knowledge exist. Regarding health literacy, a review reported persons with low health literacy to be less likely to benefit from DAs as long as health literacy was not adequately considered in the design phase [66]. One explanation for not finding any moderation

effects of eHealth literacy may be that our DA fulfilled these design recommendations to ensure comprehension [66]: Essential information was presented first [153] and numerical information was presented in crowd-figure-pictograms [100, 154] with the same denominator [154] using natural frequencies [100]. Another possible explanation for not finding an interaction with the subscales information-seeking and information-appraisal is that our respondents did not have to find the DA or appraise it [118]. Instead they were provided with the link (i.e., no information-seeking) and the DA came from a reliable source (university research project that passed through an ethics committee; i.e., at least not much appraisal skill required [118]). These two subscales thus simply may not have been relevant for successfully using the DA [118].

Health literacy did not affect knowledge at post-intervention [118] similar to crosssectional research showing self-reported health literacy to have no association with perceptions about colon cancer (risk of diagnosis, risk of death, benefit of screening) when analyses were adjusted for age, gender, race, and education [155]. Contrastingly, low health literacy has been shown to be associated with inadequate knowledge about prenatal screening tests [156]. A review including mostly studies using skill-based measures of health literacy reported a positive association between health literacy and knowledge about health services and health outcomes [113]. However, eHealth literacy and health literacy are constructs that while sharing a large overlap differ in the type of information access. Furthermore, results on skill-based measures may only be compared to our results with caution. Additionally, there may be a general 'non-association' between self-reported eHealth literacy and a performance-based measure like our knowledge index [118]. Information-Seeking, information-appraisal, and information-use showed high positive covariances [118] as can be expected for the subscales of a construct. Interestingly, all subscales showed negative covariances with baseline knowledge [118] which is in contrast to previous research [113, 156].

Moderation effect of education. Education did not moderate the effect of our DA on knowledge [118]. Similarly, education did not moderate the effect of a DA for chest pain choices on knowledge [157]. Education did not affect knowledge at post-intervention [118] contrasting previous research, in which knowledge about mammography screening was lower among women with low and medium education levels [12]. Additionally, less than 12 years of education have been shown to be associated with inadequate understanding of prenatal screening tests [156]. One possible explanation may be that we included both baseline knowledge as a predictor and post-intervention knowledge as an outcome in our model which the other studies could not do due to their cross-sectional design. Education level may be confounded with knowledge at baseline while it does not predict knowledge at a later measurement point. Contradicting this possible explanation, our results also indicated that education was not significantly associated with any of the other outcomes measured at baseline (subscales of eHEALS and knowledge). Previous research either found education to be associated with eHealth literacy [158] or, in the case of the Dutch version of the

eHEALS, found no association [159]. Another possible explanation is that, as described in more detail in Section 6.3.4, women in our sample had a higher education level than women in the population. It is possible that an association would have been found if the sample's education level was representative of the population.

6.3. Strengths and Limitations

6.3.1. Outcomes Measures

One limitation of our study is that informed choice could be conceptualised differently to the dichotomous classification of informed and uninformed deciders. Smith et al. [130] suggest grouping deciders into one of eight categories (instead of the original dichotomous categorisation model by Marteau et al. [6]) according to knowledge, attitude and screening behaviour. From these eight categories, three ordinal informed choice categories can be derived Smith et al. [130]: (1) Informed deciders are those with high knowledge behaving in concordance with their attitude, (2) partly uninformed deciders have either low knowledge or act contrary to their attitude, (3) completely uninformed deciders are those with low knowledge behaving contrary to their attitude. Informed choice as an ordinal outcome instead of as a dichotomous outcome may lead to different results and interpretations.

For an informed choice, congruence between attitude and intention/uptake is a prerequisite. Nevertheless, it is not without controversy that this is the most important congruency dimension to assess decision quality. To assess concordance in decision making, several options exist [18]. Sepucha & Fowler [160] recommend a simple match using intention preference and uptake disregarding attitude. While intention preference includes a decisional element, attitude targets the more distal instrumental and experiential outcomes of an option [18].

Theoretically, both intention or uptake can be used to calculate informed choice [6]. This makes it more flexible but at the same time poses a limitation for determining informed choice, since intention and behaviour are not equivalent (Reder et al. [35] reported a correlation of .539). Therefore, the proportion of informed choices will differ depending on whether intention or uptake is used as a third dimension. In our study, we used both intention and uptake depending on the measurement time. Accordingly, neither intention nor uptake are superior but depending on whether (non-)performance of a health behaviour lies in the future or past, only assessing one of the two is meaningful. Unfortunately, the classification model of informed choice does not give room to the coexistence of both in the decision making process. Intention and uptake are simultaneously part of the predictive model [35] but this model cannot be used to calculate informed choice.

In this study, intention to participate in the MSP within the next 3 months was used to calculate informed choice [69]. This timeframe – while being important for the validity of the question [57] – may also explain some inconsistencies between attitude and intention that were

then categorised as uninformed choices [12]. Women whose appointment was at a later date than in the next 3 months were classified as non-intenders (they intended to participate but not in the next 3 months); thus, an artificial match or mismatch between attitude and intention was created [69]. To complicate matters further, self-reported uptake is often higher than actual uptake [161] and accordingly, only health service data would have provided an unbiased uptake rate.

Another concern in calculating informed choice is that knowledge has to be dichotomised as sufficient or insufficient. Any cut-off value used for this purpose is probably flawed. We used the mid-point of the index to have a sample-independent criterion in congruence with other studies [11, 59] but other research has proposed the median [6]. Furthermore, it remains questionable whether either of these cut-offs is a valid criterion. Similarly, the dichotomisation of attitude poses a problem. Here, we again used the mid-point as a sample-independent criterion similar to Michie et al. [59]. Nevertheless, the scale has a neutral category that could equally well have been categorised as negative attitude. Sensitivity analyses could be used in the future to assess the size of the problem. The dependence of informed choice on the dichotomisation of continuous, in most cases probably non-bipolar distributed items, is a major weakness, threatening the validity of the outcome of informed choice. It would be beneficial in the future to develop a measure of informed choice that can make full use of the continuous input of knowledge and attitude dimensions.

The knowledge index contained some carefully selected facts about the MSP but could not cover the entire spectrum of possibly decision relevant facts [35, 69]. Additionally, we had to exclude one item that did not differentiate women with a high or low knowledge level [69]; while this item was inadequate to calculate knowledge, at the same time this led to a relevant knowledge aspect no longer being part of the knowledge index.

Additionally, it has to be noted that a 2-parameter-logistic model of knowledge fitted our data better than a 1-parameter-logistic model [35]. Accordingly, item discrimination is not equal across items; thus, it is essential to know which items are answered correctly and an unweighted count of the number of correct items is not sufficient. Therefore, only two approaches are feasible [35]: (1) a latent approach (allowing 2-parameter-logistic modelling; this is how we analysed the outcome knowledge) or (2) a summary index of the weighted items (with discrimination parameters used as weights [162]). Similarly to an unweighted index, a summary index of the weighted items can still be dichotomised at its midpoint for the calculation of informed choice (weighted scale range 0 to 2.8 with a midpoint of 1.4; see *Manuscript 3* in the Appendix for the exact weights of each item). In future research, this second approach may be promising for the calculation of informed choice. However, in the main analysis of this study, we followed the traditional calculation of informed choice dichotomising the unweighted knowledge outcome. This allowed comparison with previous research. To our knowledge, no latent approach to calculate informed choice – offering a more elegant solution to this problem – has been proposed to date [35].

The four semantic differentials assessing attitude covered only some advantages and disadvantages of the MSP [35]. Each woman may weigh the importance of instrumental and experiential attitude as well as the different facets within these categories differently [35]. If we would have included more than one experiential attitude item, overall attitude might have been much lower. This again may also have affected informed choice.

Regarding assessment of eHealth literacy, there is a lot of controversy surrounding the factor structure of the eHEALS [118]. Insecurity about the dimensionality of the eHEALS poses problems for the validity of this outcome and thus our results on the moderation effect. In this trial, we found the 3-factor model to have the best model fit [118]. Originally, although the eHEALS was theoretically grounded on a multidimensional model, Norman & Skinner [134] postulated a unidimensional scale. The original English (tested in a Canadian [134] and a United States sample [163]), the Dutch [159], the Japanese [164], the Chinese [165], and the Italian [166] versions all showed a 1-factor structure regardless of the diverse languages and populations they were assessed in. Contrastingly, in our study among 12th-grade-students, we found that the German version of the eHEALS comprised the two factors information-seeking and information-appraisal [137]. One reason why we found a different factor structure may be because we conducted CFA and not exploratory factor analysis (EFA). However, even though we were able to replicate a better fit of the 2-factor model over the 1-factor model in this RCT, a 3-factor model fitted best [118]. In our previous study [137], we did not conduct a CFA on the 3-factor model because for the purpose of assessing health competence, we did not have a theoretical basis to assume the third factor information-use. In future research, it would be interesting to conduct a CFA for the 3-factor model in the sample of 12th-grade-students.

It is not only a question of how many factors the eHEALS comprises but what these factors are and of which items they consist. Following our publication of a 2-factor structure [137], Neter et al. [167] reported the Hebrew version [168] to show poor fit for our proposed 1- and 2-factor models. A subsequent EFA followed by a CFA produced a good-fitting alternative 2-factor model with the factors information-seeking and information-appraisal but with a different item configuration [167]. Richtering et al. [169] found two factors in their EFA: assessing knowledge about resources and evaluation of resources. Stellefson et al. [170] with exploratory structural equation modelling found a 3-factor solution to show the best model fit. Sudbury-Riley et al. [171] using a CFA in a three country sample (United Kingdom, United States, New Zealand) reported that the eHEALS comprised 3 factors: awareness of Internet health resources, skills to access Internet health resources, and belief in one's ability to evaluate Internet health resources. Diviani et al. [172] conducted a CFA of the Italian version of the eHEALS indicating that both the 1- [134] and 2-factor model [137] showed inadequate model fit while a subsequent IRT analysis pointed to a 1-factor model [172]. Accordingly, not only whether a CFA or a EFA is conducted may influence the

results but also whether the model is tested under classical test theory or IRT. Even though CFA provides more rigorous results than EFA [173] and a theoretically assumed factor structure can only be evaluated through CFA difference tests [118], most studies relied exclusively on EFA [134, 159, 165, 168]. Accordingly, the theoretical arguments for uni- or multidimensionality received too little attention [171] resulting in theoretically unfounded interpretations of the factorial structure [174]. It remains unknown to what degree these very differing factor structures are a result of the analysis method (EFA, CFA, IRT), the theoretical models proposed in the first place, the translations, the different cultural settings, or the demographically diverse populations.

A more general problem in assessing eHealth literacy is that several (and very different) measures exist. The eHEALS is the most used tool for eHealth literacy assessment [135] and a systematic review reported 45 of 53 articles to employ the eHEALS to assess eHealth literacy [175]. Accordingly, the eHEALS can be seen as an accepted standard measure of eHealth literacy [171]. Nevertheless, the eHEALS is also an anachronistic instrument [118] developed prior to the proliferation of social media and Web 2.0 technology [171] and thus, some items may no longer differentiate well between high and low eHealth literacy [118].

6.3.2. Decision Aid as Conglomerate

It is unclear which components of the DA were responsible for its effects or whether it was an interaction of these components. This limitation cannot be overcome in a RCT testing only one intervention. The only indication regarding effectiveness of components we have stems from *Manuscript 1* which showed that crowd-figure-pictograms increase knowledge [46]. We do not know whether the knowledge increase through the DA was larger, smaller or similar to crowd-figure-pictograms alone. Regarding the effectiveness of values clarification methods, a review by Fagerlin et al. [60] reported 13 trials comparing DAs with and without these methods. Results were mixed; either no effects or positive effects for decision process improvement were found. In the future, a RCT with different versions of the DA (e.g., only crowd-figure-pictograms versus only values clarification method versus complete DA) would be useful to elucidate this question further. This would allow us to provide the most parsimonious DA to achieve informed choice and, thus, we could ensure that women would not be burdened with an unnecessarily long DA. Accordingly, there is a need to establish which components of DAs are effective [13].

6.3.3. Study Design

A major strength of this study was its design as a RCT [69]. Additionally, the follow-up period of 3 months allowed assessment over the whole decision and uptake relevant time [69]. Nevertheless, a longer follow-up period would have allowed us to assess the outcomes of screening as well as the persistence of DA effects until the next screening round after 2 years. Even though most women received the baseline questionnaire at about the time of the MSP invitation [69], some

women had not yet received this invitation resulting in a heterogeneous group regarding presence of actual decision relevance (once one has a suggested appointment, the decision becomes more relevant) and availability of usual care information (even though the brochure is available online at all times, having received it in the post will have increased availability). Only women aged 50 who were invited for the first time to the MSP were targeted by this RCT to ensure the decision was neither influenced by prior experience with the MSP nor by habit [176]. Nevertheless, this did not rule out any prior mammography experience (some women had participated in diagnostic mammograms in the past and some reported having had previous screening mammograms outside of the MSP and before the screening targeted age). Informing women about mammography screening is not a task that only becomes relevant with the onset of screening age, since, prior to that age, opportunistic screening is possible and an attitude towards screening may be formed [46].

6.3.4. Representativeness of the Sample

Compared to the estimated response rate of 15.0 % in our sample size calculation, the actual response rate was 16.3 % confirming our estimation. Contrastingly, in the paper-and-pencil cross-sectional InEMa study the response rate was 33.7 % [35]. Other studies on mammography screening in Germany reported a response rate similar to the InEMa study (37.6 % in a paper-and-pencil survey of female ensurees of a statutory health insurance aged 44 to 63 [45] and 36.0 % in a paper-and-pencil survey of 25 to 75 year old women [177]).

45.5 % had a university or university of applied sciences entrance qualification in this RCT [118] compared to 36.4 % in the InEMa study [35] and 32.9 % in the population of women aged 50 to 54 in North Rhine-Westphalia [178]. 41.2 % had an intermediate school certificate [118] compared to 43.0 % in the InEMa study [35] and 32.5 % in the population [178]. 10.4 % had obtained a secondary general school certificate in this RCT [69] compared to 19.0 % in the InEMa study [35] and 27.8 % in the population [178]. Thus, women in our sample had a higher education level than women in the InEMa study and even more so than women aged 50 to 54 in North Rhine-Westphalia.

The sample we drew from the population registries was representative except for women with a Turkish migration background which had already been recruited for the InEMa study; therefore, our results cannot be applied to this group [69]. At least partly as a result of this, nearly all women in our sample reported German as their main language [69]. As an additional reason, women whose main language was not German may have been less likely to participate due to anticipated difficulties with the German questionnaire and the German DA [69]. We asked for main language spoken at home and only 0.2 % in the control group reported only speaking a language other than German. In the DA group, 100.0 % reported German to be at least one of the main languages spoken at home. This compares to 91.7 % of women without a migration

background in the InEMa study [35] and to 80.1 % [179] in the population of women aged 50 to 54 in North Rhine-Westphalia. Even though language and migration background are not the same construct, this implies our sample had fewer women with a migration background.

Women participating in our study may have been more interested in mammography screening and thus, may have informed themselves about this screening more than the general population [69]. Rate of informed choices and knowledge may thus be overestimated. Furthermore, data were only collected in Westphalia-Lippe; regional differences cannot be ruled out. Additionally, women with extremely low eHealth literacy may not have participated; thus, a moderation effect of eHealth literacy cannot be ruled out altogether [118].

6.3.5. Statistical Analysis

For our statistical analyses, we employed latent structural equation models [69]. This had the advantage to allow us (1) to account for measurement error, (2) to test measurement invariance across time and groups enabling us to establish a crucial prerequisite for testing our intervention effect, and (3) to deal with missing values [69]. However, this was only possible for outcomes with several indicators and as described in Section 6.3.1, we still lack a latent approach towards informed choice.

6.4. Implications

Informed choices are important and have to be supported. Our DA is an effective tool to improve the rate of informed choices [18]. It was made accessible to the public on the BARMER website and we recommend the use of this DA for first-time MSP invitees to improve informed choices. As practice implications, women invited to the MSP should be informed about the existence of our evidence-based RCT-evaluated DA and how to access it. To make the DA accessible to all women invited to the MSP, it should be translated into all languages a reasonable proportion of targeted women speak (e.g., Turkish). Additionally, a version for blind and visually impaired women should be provided. Our DA should be continually updated to the latest evidence. This is especially important in a DA for a health intervention where the margin between beneficiality and harmfulness is as thin as in mammography screening as new research results may change the risk-benefit ratio.

As an ethical as well as a health policy implication, it is debatable whether a neutral DA may be provided by the same organisation that is also offering the screening [3]. Providing the information through the screening organisation is practical because the DA can be attached to the invitation to the screening. As long as uptake rates remain sufficiently high, this poses no problem but when uptake declines under a crucial level – even if the goal of informed choice is to be superior to the goal of a high uptake rate [40] – the whole programme becomes unsustainable

[3]. This puts the organisation in a dilemmatic situation [3]. Therefore, programme independent DAs should be provided to ensure unbiased selection and presentation of scientific evidence.

As a theoretical implication, we propose a model integrating the effect of the DA on the dimensions of informed choice within the predictive model of the Reasoned Action Approach (see Figure 1). In this model, barriers, norms, and attitude predict intention, which in turn predicts uptake of the MSP. In line with the Reasoned Action Approach, knowledge, eHealth literacy, and education can be conceptualised as background factors [57]. Knowledge, as one dimension of informed choice, is hypothesised to be a predictor of attitude, norms, and barriers and may influence these. All dimension of informed choice are depicted separately because informed choice cannot be conceptualised as a single construct in a predictive model as it includes dimensions that are relevant at different times in the decision process. We partially tested the pathways in this model. (1) We assessed which constructs our DA affected (solid pathways on the right of Figure 1; as described previously, the DA had an effect on knowledge and intention but not on uptake and only an effect on attitude at follow-up). (2) We tested wether the effect of the DA on knowledge was moderated by eHealth literacy and education (this was not the case). Future research will have to elucidate to what degree the effect of the DA is mediated by knowledge, barriers, norms, and attitude and to what degree barriers moderate the effect of intention on uptake. Further implications for research are described in Section 6.5.

6.5. Future Research

New Brochure. Since the end of our RCT, in 2015 a new MSP information brochure has been introduced [180] and in 2017 this brochure was further developed into a paper-based DA [181]. This paper-based DA has not been evaluated in a RCT yet. Additionally, a concept for a future online version of this DA has been developed [84]. It will be interesting to see how the paper-based DA fares as usual care compared to our Internet-Based DA and how the online version of the DA (once it is available as a part of usual care) compares to our DA.

Affect. The influence of affect on information processing should be elucidated in future research [69]. Previous research showed the importance of affect compared to information [182]. Expected-utility-type theories like the Reasoned Action Approach ignore the role of affect in the decision making process [182]. Specific to mammography screening, decisions involve being exposed to counterintuitive evidence [183]. One example for a counterintuitive piece of information is over-diagnosis (this conforms with the reactions in our interviews for IMQ development). Additionally, when women perceive breast cancer as a severe condition, they show reduced understanding of screening statistics [183]. Accordingly, when the consequences of a decision are affect-rich (e.g., fear of breast cancer), people engage heuristic processes and as a consequence, disregard probabilistic information [184]. This has also been confirmed in focus group discussions where women

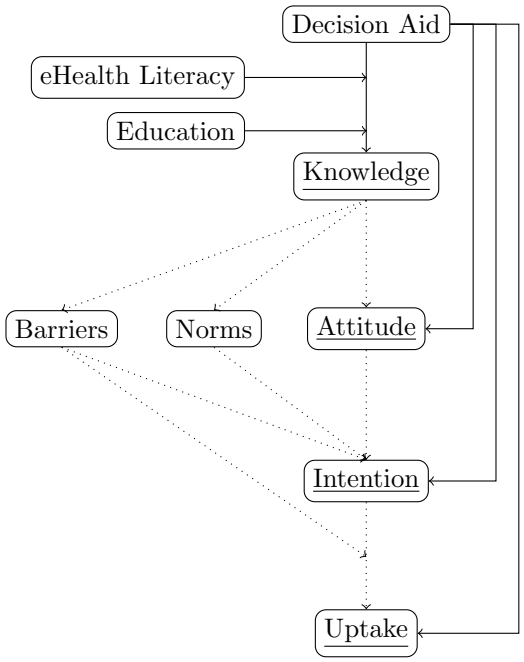

Figure 1. Hypothesised moderated mediation model for integrating the effect of the DA on the dimensions of informed choice within the predictive model of the Reasoned Action Approach (Figure based on Fishbein & Ajzen [57]). Tested pathways are depicted as solid lines (irrespective of statistical significance), untested pathways as dotted lines. Dimensions of informed choice are underlined. Barriers include the subscales 'assumptions about the MSP' and 'importance of the MSP'.

reported affective factors to have a large influence on their choices about mammography screening [185]. Women who tend towards mammography participation rated information about advantages as more relevant while women who do not tend to participate evaluated advantages and disadvantages as equally important [186]. Therefore, balanced information does not equal balanced processing [186]. Information on mammography screening conflicting with previous attitudes is ignored; women already have these attitudes prior to the arrival of screening programme information [187]. When women see breast cancer as a highly severe condition, visual aids (e.g., crowd-figure-pictograms) showed no benefits [183]. Instead women relied on established beliefs and were less motivated to engage with visual aids [183]. Both fear of breast cancer and existing beliefs about mammography screening hinder comprehension of new information negatively affecting knowledge and informed choices [183]. Therefore, affect should be assessed and tested as a moderator in future research. One possibility to enable women to better process the subsequent information would be to influence affect in an initial module of the DA.

Results of the MSP. Most trials on DAs fail to assess long-term effects [130]. It would be interesting to assess the long-term effect of our DA on quality of life and health outcomes as well as to assess the effect of the different outcome groups of screening (false-positives, negatives, true-positives) and how these interact with the DA [69]. We assessed screening outcomes and the result of further diagnostics but in the short time span of our RCT too few events for any calculations occurred [69].

Moderated Mediation Model. In the proposed moderated mediation model, the untested pathways (see dotted lines in Figure 1) should be estimated to map the effect of the DA within the predictive model of the Reasoned Action Approach [57]. Establishing a model that includes all relevant moderators and mediators and not just singular pathways will allow us to assess the mechanisms by which the DA influences the dimensions of informed choice. Additionally, it will allow us to determine how the dimensions of informed choice affect each other in a predictive model of behaviour. The results of this moderated mediation model could help improve the DA because this would allow us to develop a stronger theoretical basis for the targets of the different components of the DA.

Circular Process. Exposure to information materials and eHealth literacy influence each other [118]. Being exposed to credible online health information correlates with higher eHEALS levels [188]. Women with higher eHealth literacy find better information sources which in turn increases their eHealth literacy [118]. This way a DA can be an intervention to increase eHealth literacy and, thus, possibly improve informed choices in other health areas. Therefore, in future research, eHealth literacy should not only be assessed as a baseline characteristic but also at all follow-ups.

Latent Transition Analysis for Informed Choice. So far, we have only looked at informed choice from a traditional classification perspective statistically testing this with χ^2-tests. Future research should explore a latent transition analysis (a latent Markov model where the latent variables as well as the observed items are categorical). Two approaches are possible: (1) the three dichotomised dimensions are used as indicators (knowledge (high/low), attitude (positive/negative), intention/behaviour (yes/no)) or (2) the dichotomised items of all three dimensions are used as indicators. In the first approach, at each of the three measurement points, three binary variables form the latent status informed choice. In the second approach, six binary knowledge items, four binary attitude items and one binary intention/uptake item form the latent status informed choice. It will be interesting to see, which of all the possible combinations of indicators are of relevance (i.e., which combinations our participants show); this will allow a more differentiated analysis than our previous approach only looking at informed versus uninformed choices. Additionally, this approach will allow us to see which transition pathways (i.e., movements from one latent status to another over time) are important and how this is influenced by the DA.

6.6. Conclusions

This dissertation project was the first to develop and systematically evaluate a DA for the MSP [18, 69]. To achieve this, it enveloped the results of three other research projects for instrument development and testing of crowd-figure-pictograms. The finding that crowd-figure-pictograms by themselves increase knowledge made the decision to include them in the DA not just theoretically but also empirically grounded. Having developed an adequate questionnaire to assess informed choice in mammography screening is an important step in establishing informed choice as a standard outcome in this area of research [35]. Having provided a translation of the eHEALS with further information on its factor structure enabled us to assess eHealth literacy – an important possible moderator of DAs. Finally, the results of this RCT are important for the following reasons: They show the DA to (1) be acceptable to women, (2) increase the proportion of informed choice, increase knowledge, and decrease decisional conflict [69], and (3) be effective in increasing knowledge regardless of eHealth literacy or education level [118]. Women of all eHealth literacy levels profit from the DA [118]. Thus, the DA developed in this project is a comprehensible information and support tool for women deciding whether to participate in the MSP [69, 118]. The DA is publicly available on the website of the BARMER. In sum, the presented research cumulus is of high public health relevance since not only the importance of informed choice was highlighted and an adequate instrument for its measurement was developed but especially because it offers at least part of a solution for counteracting uninformed compliance in mammography screening through the provision of an effective DA.

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Appendix

Declarations

Ich erkläre, dass ich diese Arbeit selbständig verfasst und keine anderen Quellen und Hilfsmittel als die angegebenen benutzt habe. Ich versichere, dass die vorliegende Arbeit nicht als Prüfungsarbeit für eine staatliche oder andere wissenschaftliche Prüfung eingereicht wurde und ich bisher keine weiteren Versuche zur Promotion unternommen habe.

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Publication List of the Candidate

Submitted / in Press

Berens, E.-M., Kaucher, S., van Eckert, S., **Reder**, M., Kolip, P., & Spallek, J. (2018). *Knowledge about mammography screening in Germany by education and migrant status – results of a cross-sectional study (InEMa).* Manuscript submitted for publication.

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Reder, M. & Soellner, R. (2013, September). *eHealth Messung und was wir daraus lernen können - Ein fähigkeitsbasierter Ansatz zu Online Informationssuche und Informationsbewertung.* Paper presented at the 14th Tagung der Fachgruppe Pädagogische Psychologie, Hildesheim, Germany.

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Posters with Peer-Review (Ordered by Year)

Noetzel, S., Greve, W., **Reder**, M., Hauenschild, K., Laukner, J., & Ohnesorge, L. (2018, June). *Einstellungen von Lehrenden zu Inklusion in der Schule - Heterogenität des Konstrukts.* Poster presented at the 11th Tagung der AG Inklusionsforschung, Flensburg, Germany.

Mojzisch, A., Frisch, J., Doehne, M., **Reder**, M., & Htäusser, J. (2017, July). *Combined effects of network centrality and group identification on daily stress.* Poster presented at the 18th General Meeting of the European Association of Social Psychology, Granada, Spain.

Reder, M., Soellner, R., Machmer, A., & Wilz, G. (2014, August). *How effective is telephone-based psychotherapy for family-caregivers of people with dementia? A randomised controlled trial.* Poster presented at the 28th Conference of the European Health Psychology Society, Innsbruck, Austria.

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