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Co-creation of a health literate-sensitive training and conversation aid to support shared decision-making in maternity care

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ABSTRACT

Background: Maternity care increasingly aims to achieve Shared Decision-making (SDM), yet seemingly not to the benefit of clients with low health literacy (HL). We developed an SDM training for healthcare professionals (HCPs) and a conversation aid to support HL-sensitive SDM in maternity care.

Methods: The training and conversation aid were based on previous needs assessments and expert consultation, and were developed in co-creation with clients (n = 15) and HCPs (n = 7). Usability, acceptability and comprehension of the conversation aid were tested among new clients (n = 14) and HCPs (n = 6). Acceptability of the training was tested among midwifery students (n = 5).

Results: In the co-creation sessions, clients reported to expect that their midwife becomes acquainted with their general values, priorities and daily context. Clients also emphasized wanting to be supported in their preferred decisional role. User test interviews showed that clients and HCPs were positive towards using the conversation aid, but also apprehensive about the time it required. The user test of the training showed that more attention was needed for recognizing and adapting information provision to clients' HL level.

Conclusion and innovation: The newly developed conversation aid and training have potential to support HCPs and clients in HL-sensitive SDM.

1. Introduction

Clients in maternity care are expected to participate in many preference-sensitive decisions related to pregnancy and birth, thereby considering not only their own preferences, but also what they think is best for their child. [1] Preference-sensitive decisions include, for example, the decision about pain relief during labor and the decision about the place and mode of birth, for which more than one reasonable option is described in relevant clinical guidelines. [2] Involving clients in these decisions is considered key to client-centered care. Shared Decision-making (SDM), in which healthcare professionals (HCPs) and clients share the best available evidence and clients are supported to consider options in light of their goals and preferences, is considered as the preferred conversational model. [3]

SDM requires clients, at least to some extent, to being able to access, understand, appraise and apply benefit/harm information to make decisions, as well as to effectively exchange information with HCPs, such as midwives, obstetricians and maternity care nurses. [4,5] These skills correspond to the concept of "health literacy" (HL). [6] Systematic reviews demonstrated the beneficial effects of both training of HCPs [7] and patient decision aids [8] on the participation of patients in decision-making in various clinical settings. However, effects among patients from more socially disadvantaged groups or patients with lower functional HL (i.e. basic reading and writing skills) remain uncertain [9], since most of the trainings and (inter)national patient decision aids, also in maternity care, have not been designed for, or evaluated among, low

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HL clients. [10]

Decision-making in maternity care can be distinguished from other types of clinical decision-making, since maternity care is founded on the notion that pregnancy, birth and the postpartum period are primarily 'healthy' physiological processes, and decisions are made for the pregnant person as well as the child. [11] Also, final decisions are often postponed to the moment of labor. It is considered beneficial to adequately inform clients about the options they have. [12] The question remains if this translates to SDM in light of the provisional nature of decisions around labor as decisions depend on (medical) circumstances, mode and place of birth. Furthermore, maternity care professionals are generally used to intensive multidisciplinary collaborations, which may influence how clients are involved and how the preferences they expressed are effectuated. In the Netherlands, for example, maternity care is organized in two echelons; midwife-led, community based care (first echelon) and obstetrician-led, hospital based care (second echelon). Most pregnant persons are considered to be healthy ('low risk') and therefore receive antenatal care from a community midwife from the beginning of their pregnancy. When complications arise and become threatening during birth, or when pharmacological pain relief is requested, referral to the second echelon (i.e. obstetricians) is necessary. This means that the decision-making process can be transferred from the community midwife to specialist care. [13]

Our earlier needs assessment study among clients in Dutch maternity care showed that those with low functional HL levels and primigravidas mainly perceived difficulties in finding reliable information, understanding probabilistic information, constructing preferences based on benefit/harm information, and preparing for consultations. [14] Our needs assessment study among maternity care professionals showed that they experienced difficulties in supporting low HL clients, for example with regard to estimating whether the client understands information in general and with low HL clients specifically [15]. Other studies have also shown increased chances for misunderstanding between HCPs and patients among HCPs who in general lack recommended skills to communicate with low HL patients. [16] Training in HL-sensitive communication has been shown to improve HCPs' skills in enhancing patient decision-making autonomy and to strengthen their intention to apply HL-sensitive communication. [16]

This study aimed to develop an SDM training for maternity care professionals and an SDM tool that would support HCPs and clients with varying HL levels in SDM. In Dutch maternity care, multiple preferencesensitive decisions are made, and HCPs work interdisciplinarily to effectuate those decisions. Given these context and aims, our central starting point was to develop a generic structure for the SDM tool to support different decisions during pregnancy and birth and in the postpartum period.

2. Methods

2.1. Study design

This study describes the systematic development of an SDM training and tool building on our earlier needs assessment studies among clients and HCPs. [15,17] We combined elements of the Intervention Mapping protocol (IM) [18] with User-centered design (see Fig. 1 for a schematic overview of the study design). [19] Experts were consulted to discuss and prioritize objectives. We further held co-creation sessions and user testing interviews with clients (women and partners) and HCPs to test the SDM training and tool respectively. In all activities, we took into account the fact that the tool should be primarily usable during consultations (i.e. a conversation aid) and should be used during the developed SDM training for HCPs. Key features for systematic development processes of the conversation aid included: scoping and design; development of a prototype; testing with clients and HCPs in an iterative

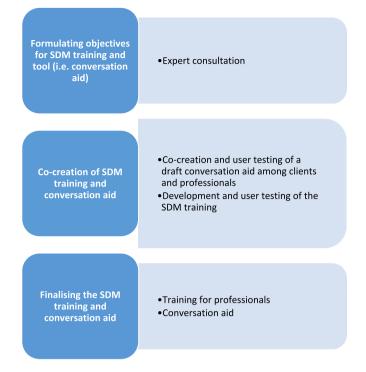


Fig. 1. Schematic overview of the study design.

process; and production of a final version of the training and conversation aid. [20] Supplementary file 1 provides a description of the SDM training's and conversation aid's final version.

2.2. Participants

The study population consisted of clients and HCPs in Dutch maternity care, integrating care from obstetricians, obstetric residents, obstetric nurses, midwives, maternity care assistants, lactation consultants, and youth health care specialists. We included women with a gestational age of 25 weeks onwards and women who had given birth in the past year, and their partners. Clients were approached via an online recruitment panel (Flycatcher), social media platforms, our personal network, a maternity care client panel, via snowball sampling (where study participants invite other potential participants), and were personally recruited by the first author (LM) in the waiting rooms of a Dutch midwifery care practice. Low HL women who had participated in our earlier study [21] and gave consent to be approached for future research were also invited to participate.

In all activities, we ensured that low HL clients were adequately represented. We orally assessed clients' functional HL prior to participation by phone using the Short Assessment of Health Literacy-Dutch (SAHL-D) and the Newest Vital Sign-Dutch (NVS-D). We used the SAHL-D to estimate clients' basic understanding and reading skills and the NVS-D to also assess basic skills in using numbers in health-related information. Because of time constraints and for practicality, we only assessed SAHL-D when women or partners scored high on NVS-D. Participants who scored low on either NVS-D or SAHL-D were considered as low functional health literate. A SAHL-D score lower than 9 and a NVS-D score lower than 4 were considered as low functional health literate. [22,23]

HCPs were approached via LinkedIn and via an announcement on the Royal Dutch organization of midwives' website. Any HCP consulting directly with clients was eligible to participate in the co-creation sessions and user tests. The expert consultation included HCPs, researchers and trainers, who were members of the research project group.

Written informed consent was obtained from all participants prior to the first co-creation session or user test interview. All co-creation sessions were held online and were recorded and summarized. User test interviews with clients were held online or at their home. User test interviews with HCPs were all held online. All interviews were recorded and transcribed literally. All participants received a gift voucher after participation.

2.3. Procedures and measures

2.3.1. Expert consultation

In line with IM, previous needs assessments were used to summarize challenges among clients and HCPs in SDM, and to formulate these challenges as desired changes, e.g. "HCP discusses benefits and harms including probability information with clients". In preparation for the expert consultation, objectives for the conversation aid and training were formulated by breaking down each desired change by answering the following question: "What does the HCP and/or client need to do to achieve this change?" These objectives were then organized according to the following determinants: knowledge or communication skills, selfefficacy, risk perception, or awareness of and attitude towards SDM. For example, an objective regarding a desired change in communication skills was "HCP explains necessary information in an understandable manner". The experts chose the most relevant and feasible objectives during the expert consultation session. During expert consultation, a short presentation was given about SDM followed by our objectives. Note that the objectives may relate to particular steps in SDM, but need not. Next, HCPs were asked to rank the objectives from 'most difficult to achieve' to 'least difficult to achieve' by means of a short survey (findings reported elsewhere; [15].

In consultation with the research project group, we also selected an example case about which basic information was included in the conversation aid, in addition to the generic structure that aimed to facilitate SDM for any decision topic. We chose pain relief during labor because it is, in principle, discussed with all clients in Dutch maternity care and is seen as a preference–sensitive decision. According to the Dutch National Care Standard Integrative Maternity Care, pain relief options should be discussed before labor starts as the decision is related to the chosen place for birth and (clinical) circumstances during labor. [2]

2.3.2. Co-creation of a conversation aid

We aimed to design a generic structure for the conversation aid which could be used to create choice awareness and stimulate conversations about preference-sensitive decisions prior to birth and in the puerperium stage (e.g. decisions regarding infant feeding). Content for the decision 'pain relief options during labor' was used as an exemplar case. To this end, existing pain relief decision aids and findings from systematic reviews [24,25] were used, and all text was written in plain language (in Dutch: 'B1 level') with the assistance of a plain language expert.

Building on user-centered design principles [19], clients and HCPs participated in co-creation sessions to develop the generic structure for the conversation aid.

Co-creation sessions were separately organized with women, with partners, and with HCPs. Further, we conducted co-creation sessions among low HL women separately from high HL women to be able to pay attention to supporting low HL women with the digital assignments. For pragmatic/logistical reasons, the first co-creation session was performed with higher HL women, since the first women that were included in the study were the ones with higher HL. We then built on the design directions formulated with this group of high health literate women. We investigated additional needs for support in the co-creation interviews among low health literate women. We also conducted co-creation sessions with partners to explore more broadly how they envision their role in SDM, since less is known about partners' view on SDM and decisionsupport in maternity care. The co-creation sessions with partners and low HL clients were eventually held as individual interviews for practical reasons, i.e. difficulties to schedule sessions with all participants on the same date. Furthermore, two co-creation sessions were held with HCPs to achieve greater variation in professions and perspectives, while keeping the number of participants per session to no more than five.

Initial design directions were developed based on the ideas generated in co-creation sessions with high HL women. The sessions with low HL women, partners and HCPs built on the sessions with high HL women and mainly aimed at exploring additional needs and evaluating prototypes of the conversation aid and draft content of the training. A final prototype was developed in an iterative process according to the cocreation sessions. The co-creation sessions and co-creation interviews were all held online due to COVID-19 restrictions. They were guided by LM (health scientist) and LS (industrial designer; research assistant). We used Miro (online whiteboard) to support the creative digital assignments.

2.3.3. User testing the conversation aid

Based on the findings and initial design directions in the co-creation sessions, a final prototype of the conversation aid (Supplementary file 1, Figs. 1–6) was developed. The actual user tests were conducted among a new group of clients and HCPs and aimed to assess usability, acceptability and comprehensibility of the conversation aid.

We assessed participants' navigation strategy according to our interview protocol (instructions and questions asked during the user test interview can be found in Table 2) and problems as indicators of usability, and their information preferences and intention to use the conversation aid as indicators of acceptability [26]. Regarding comprehensibility, we assessed participants' perceived understanding of the purpose and content of the several elements of the conversation aid.

2.3.4. Development and user testing the SDM training

The SDM training was developed by the research project team. An existing general SDM training as provided in Amsterdam UMC was used to develop the basic content. [3,27] We adapted the content where needed, based on the findings from co-creation sessions and user testing of the conversation aid, since the conversation aid was also incorporated in the training. Furthermore, based upon our previously developed objectives, we expanded the basic content of the training with elements on HL-sensitive communication and risk communication. For example, how to recognize low HL and use the teach-back method, and how to present probability information in numbers with icon arrays instead of using verbal terms only. Finally, the acceptability of the training was pilot-tested among midwifery students (n = 5).

The training consisted of a presentation by the trainer about SDM theory and HL-sensitive communication, and a role-play with an actorclient according to a script (main part of the training) where participants could practice SDM skills and received feedback from the trainer, the actor-client and their co-participants. (See Box 1.). The basic content of the presentation focused on the main steps of SDM/decision-support, namely: (1) explaining the aim of the conversation and creating choice awareness; (2) explaining options and their benefits and harms; (3) discussing the client's preferences and supporting in deliberation; (4) discussing the client's wish to make the decision, to make or defer the decision, and discuss follow-up. The script contained information about the actor-client's gestational age and medical condition, and in-structions for the actor-client to portrait specific inadequate HL skills. The total duration of the training was three hours.

2.4. Data analysis

To guide the analysis of the co-creation sessions, we used the Data-Information-Knowledge scheme as used by Sanders and Stappers (2012). [19] After each session, research assistants LS or MW (both industrial designers) summarized the data and discussed this in The training consisted of a presentation by the trainer about SDM theory and HLsensitive communication, and a role-play with an actor-client according to a script (main part of the training) where participants could practice SDM skills and received feedback from the trainer, the actor-client and their co-participants. The basic content of the presentation focused on the main steps of SDM/decision-support, namely: (1) explaining the aim of the conversation and creating choice awareness; (2) explaining options and their benefits and harms; (3) discussing the client's preferences and supporting in deliberation; (4) discussing the client's wish to make the decision, to make or defer the decision, and discuss follow-up. The script contained information about the actor-client's gestational age and medical condition, and instructions for the actor-client to portrait specific inadequate HL skills. The total duration of the training was three hours.

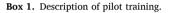


Table 1

Background characteristics of clients participating in the co-creation sessions and user test interviews.

	Co-creation sessions high health literate women $(N = 4)$	Co-creation interviews low health literate women $(N = 3)$	Co-creation interviews partners (N = 8)	User test interviews high health literate women (N = 7)	User test interviews low health literate women $(N = 4)^{b}$	User test interviews partners (N = 3)
	Median (range)/ N	Median (range)/N	Median (range)/ N	Median (range) /N	Median (range) /N	Median (range) /N
Age	31 (30–35)	33 (28–37)	33 (29–34)	33 (29–39)	34 (30–35)	35 (33–35)
Educational level						
Intermediate	-	1	-	2	4	1
vocational education						
Bachelor degree or	4	1	8	4	-	2
higher						
Marital status						
Married/living	4	1	8	5	4	3
together with						
partner						
In relationship/living	-	1	-	1	_	-
apart from partner						
Health literacy ^d						
NVS-D	6 (6–6)	4 (3–4)	6 (6–6)	-	5 (3–5) ^a	6 (5–6)
SAHL-D	-	10 (6–13)	12 (9–13)	12 (10–13) ^c	8 (6–9)	13 (10–13)
Parity						
(partner of)	2	2	3	3	1	-
primigravida/						
primipara						
(partner of)	2	-	5	3	3	3
multigravida/						
multipara	22 (24 A V)			4.0 (= 0.0)		
Number of weeks	33 (31–34)	13 (13–13)	33 (21–37)	18 (7–29)	26 (13–36)	32 (32–32)
pregnant			aa (a. (i)			aa (a. (i)
Number of weeks after birth	29 (13–44)	-	28 (3–44)	12 (2–12)	-	23 (2–44)

^a 1 missing value.

^b 1 respondent participated in our earlier study.

^c 5 missing values.

^d mean SAHL-D scores lower than 9 and/or mean NVS-D scores lower than 4 indicated low functional HL levels.

Table 2

Background characteristics of professionals participating in the co-creation sessions and user test interviews.

	Co-creation sessions HCPs $(N = 7)$	User test interviews HCPs $(N = 6)$	
	Median (range)/ N	Median (range)/ N	
Age	50 (27-62)	44 (28–60)	
Work experience	13 (0.6–16)	8 (3–28)	
Profession			
Client advocate	1	-	
Primary care based midwife	2	-	
Hospital based midwife	1	1	
Obstetrician	-	3	
Resident	1		
Lactation consultant	2	1	
Maternity care assistant	-	1	

consultation with the research team. Together, we moved from data to information by interpreting the data, identifying patterns in the interpretations, and deriving main topics. User tests of the prototypes and final prototype of the conversation aid were transcribed literally and analyzed by LM inductively using MAXQDA. Excerpts from the transcriptions related to acceptability, usability and comprehensibility were categorized. Based on the analyses, it was assessed which additional adaptations needed to be made to further improve the conversation aid.

3. Results

3.1. Background characteristics of participants

Tables 1 and 2 describe the background characteristics of the cocreation's and user test's participants.

3.2. Outcomes expert consultation

Box 2 describes the objectives as finalized during the expert consultation. The expert group prioritized the importance of creating choice awareness as starting point for a conversation (objective 1) and facilitating the discussion about benefits and harms of options. As for objective 2, it was stressed that HCPs should create space for questions and uncertainties clients bring to the consultation. By adapting the information to clients' level of knowledge and filling in clients' knowledge gap (objective 3), the HCP should ideally avoid information overload and at the same time avoid overestimating clients' prior knowledge. The experts also stressed that the HCP could take on the role as a medical expert when coaching clients in the value clarification process (objective 4), while taking into account the provisional nature of decisions. This latter was stressed, since final decisions around labor depend on several factors such as changing (medical) circumstances, and the mode and place of birth, and therefore experts found it important to manage expectations of clients in this respect. In this process, it was emphasized that HCPs should incorporate clients' personal circumstances and values in decision-making. Furthermore, the experts mentioned that, in general, it is important that HCPs have a conversation with their clients about their clients' personal background, (cultural) beliefs, uncertainties, wishes and needs regarding birth. Finally, professionals mentioned the importance of informing clients in an understandable manner, and checking understanding by, for example, applying the teach-back method (i.e. asking patients to restate given information in their own words), and actively providing reliable HL-sensitive informational materials to clients (objective 3 and 5).

3.3. Outcomes co-creation sessions to develop a conversation aid

Table 3 provides an overview of key insights from all the co-creation sessions, structured along the corresponding aims and the methods used. A consistent theme across low and high HL women and partners, was the expectation that midwives are ideally well-informed about clients' general values, priorities and daily context and that midwives should help clients to integrate this into decision-making. HCPs also stressed the importance of getting to know the client through conversations about the client's socio-emotional, psychological and cultural background, how the client thinks about decisions needed to be made, as well as about the transition of becoming a parent.

Women and partners expressed a need to be supported in their preferred decision-making role. Most clients and partners wanted to eventually make decisions themselves, stressing a certain sense of autonomy but also a wish that the HCP takes their preferences and values into account. Professionals also emphasized client's autonomy during decision-making. However, most partners expressed that they had not felt included in the decision-making process with regard to several decisions made, while they would have wanted to be involved.

Women and partners expressed that a neutral-looking conversation aid could be used in a personal conversation with midwives (a 'conversation aid') to support them in their preferred decision-making role. However, women, partners, and professionals also mentioned that limited time could be a barrier to use a conversation aid during consultations.

Another consistent finding among clients and HCPs related to the need to adequately and neutrally inform clients about the fact that there is choice (choice awareness), and about the available options. We also found that there was a need for flexibility, as clients' preferences were thought to change during pregnancy.

3.3.1. Design implications for the conversation aid based on the co-creation sessions

Based on the findings among clients with higher HL, five initial design directions were developed for the conversation aid, to be used in the consultation between HCPs (e.g. midwives) and clients. Designs focused either on informing or organizing options and decisions, or on responding to clients' values and preferences. After evaluating these design directions in the co-creation sessions with low HL women, partners and HCPs, we developed one prototype. We focused on a conversation aid to be used during the consultation and available for access at home, instead of an aid to be used to prepare for the consultation (e.g. by

Box 2

Overview of key objectives for training and the conversation aid as formulated during the expert consultation.

Objectives clients	Objectives HCPs
1. Clients are aware of their choice and available options.	 HCPs identify the starting point of the conversation by asking questions and checking clients' prior knowledge and their choice awareness for a specific decision to be made.
2. Clients discuss benefits and harms of options with their HCP.	2. HCPs create space to discuss questions and uncertainties.
 Clients have sufficient information about probabilities, benefits and harms to weigh options. 	 HCPs identify knowledge gaps among clients, inform clients in a comprehensible manner and adapt information provision to clients' needs and comprehension level.
 Clients feel heard and ask questions to HCPs and convey their uncertainties, needs and wishes. 	 HCPs initiate process of weighing benefits and harms of options and support clients by using the conversation aid.
	HCPs support clients in a non-judgmental manner to formulate preferences and create space to discuss preferences.

Table 3

overview of objectives and methods used in co-creation sessions and key insights.

	Objective	Methods	Results and key insights
Session 1a high HL women	To explore what women find important regarding weighing options	 Give a top 3 of the most important objectives to address in the conversation aid Put pictures that resonate with important individual values in a circle from most important to least important 	According to clients, midwives need to know client's prior knowledge and persona characteristics, such as religion, family composition, other parties involved in decision-making, medical background, experiences with earlier pregnancies, and
	To formulate requirements for the generic conversation aid and how this could be	- Formulate wishes and requirements for the conversation aid	preferred role of client in decision-making
	supported with the conversation aid		According to clients, midwives need to:
			- Continuously offer choice,
			- Treat the client as an equal partner,
			- Be transparent about options,
			- Ask 'why' the client chose for a particular option
			- Discuss existing questions and fears
			According to clients, the following individual values should be taken into accourduring consultations:
			- Clients' sense of control
			- Mother and child's health during pregnancy
			- Sense of autonomy or importance that their interests and preferences will be
			incorporated in decision-making
			- Interaction with midwives (feeling supported in their preferences)
			According to clients, the conversation aid needs to provide:
			- Understandable (probability) information about benefits and harms in
			multimedia
			- Experiences of others (reviews)
			- Flexibility (should not fix the decision)
			- A secure environment for the client and midwife
			According to clients, the conversation aid should be/have:
			- User-friendly
			- Digital, clear & consistent information
			 A friendly atmosphere
ession 1b high HL women	To create design ideas for the conversation aid	 Think of three ideas for the 'how to'-statements'¹ formulated according to the outcomes of the first session. For example 'How to make sure the midwife 	Clients emphasized:
women	uiu	knows enough about me?' or 'How to make sure the midwife knows my	- Questionnaire to fill in prior to consultation
		preferences?'	- Table and videos about benefits and harms
		- Sketch the ideal conversation aid in Miro and present these ideas in small	- Save and adapt preferences and provisional decisions
		groups	- Rank options
		- Participants' sketches were professionally designed by LS to use in the	- Overview of topics and decisions per consult
		subsequent sessions	- Invitation to use the app at home and to read more information at home
			- Visualizations
			- Reviews of others
ession 2 low HL women (individual	To explore additional needs for support	 Put pictures that resonate with important values in a circle from most important to least important 	Clients wanted midwives to:
interviews)	To evaluate design directions which were	important to least importantDiscuss the relevance of the wishes and requirements for a conversation aid	- Provide trustworthy information to read at home
111(1) VIC VV3J	developed based on results of co-creation	formulated in session 1 and add additional wishes and requirements	 Support them in weighing options in a personal conversation
	sessions 1a and 1b	 Mention what you like and dislike about the ideas designed by participants in 	- Remind them of initial decisions
		session 1 and whether you would use such conversation aids	- Be familiar with their general lifestyle, (mental) health, family life
		· · · · · · · · · · · · · · · · · · ·	- Support them in their preferred decision-making role
			Clients positively evaluated design directions:
			chents positivery evaluated design directions.

⁻ All information provided on one platform and accessible at all times

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Table 3 ((continued)

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	Objective	Methods	Results and key insights
			- Use for conversations with midwives
			 Note down questions digitally
			 Useful to share what client finds important
			 Should allow to express preferences
			- Understandable terminology, visual material, overview of information
			Adaptations needed to conversation aid, according to clients:
			- Should be preferably shorter
			- Possibly leave out experiences of others
			- Further simplification of information on benefits and harms of options
			- Possibly leave out the option to fill in questionnaires
			- More guidance to express values
			- No filtering information of according to answers of clients
Session 3 partners	To broader explore how partners vision	- Finish the sentence 'Sharing a decision with a healthcare professional means"	Role of partners:
(individual interviews)	their role in SDM	and elaborate why you chose this sentence. Additional questions were asked by the moderators, e.g. "How were you involved in the decision-making process?"	- Most partners did not feel involved by the professional during consultations
	To explore additional needs for support	- Put pictures that resonate with important values in a circle from most	- Supportive role in and outside the consultation (e.g., finding/using informatio
	I I I I I I I I I I I I I I I I I I I	important to least important	together; remembering information; concretizing decisions)
	To evaluate concepts which were developed	- Mention 3 things that you like and dislike about the ideas designed by	- The midwife should respect the decision made by the partner and pregnant
	based on results of the co-creation sessions	participants in session 1 and whether you would use such conversation aids.	woman
			Partners positively evaluated design directions:
			- Stimulates to think about decisions
			- Functions as a checklist for partners
			- Presents decisions in a chronological structure
			- Can be used during consultation or to prepare a consultation
			- Helpful to understand terminology
			Adaptations needed to conversation aid:
			- Should not give advice or make final decisions
			- Lack of time during consultation (e.g. to show videos)
			- Seems to focus on pregnant women
			- Should be a website (without log in)
			- No need for experiences of others
Session 4 HCPs	To explore additional needs for support	- Finish the sentence 'Shared decision-making means to me' and elaborate	Needs for support emphasized by HCPs were:
	To avaluate concents which were developed	why you chose this sentence.	To discuss how the client facle shout the desisions
	To evaluate concepts which were developed based on results of the co-creation sessions	- Discuss the importance of the change objectives for the conversation aid and	- To discuss how the client feels about the decisions
	based on results of the co-creation sessions	training	- To get to know the client
		- Mention in a timeline what you need to know about the client, how you address	- To pay attention to the transition involved in becoming a parent
		knowledge gaps, and what decisions are discussed in consultations	- To provide information in a non-normative way
		 Mention what you like and dislike about the ideas designed by participants in session 1 and whether you would use such conversation aids. 	 To gauge client's level of understanding of the information Extra time for lower HL clients
			Important aspects emphasized in relation to the conversation aid:
			- Summarize and visualize information
			- Summarize and visualize mormation
			 Should actively ask questions and prompt client to ask questions
			 Should actively ask questions and prompt client to ask questions Interactive: personalize options by asking questions
			- Interactive: personalize options by asking questions - Plain language
			- Fun to use
			- Takes a lot of time, therefore adaptations are needed to replace or reduce time

for other parts of a consultation

¹ How-to-statements are statements formulated by the participants to achieve their needs. For example: How can you present benefits and harms in an understandable way? How can you define and express your preferences? [28]. Van Boeijen A, Daalhuizen J, van der Schoor R, Zijlstra J. Delft design guide: Design strategies and methods 2014.

Table 4

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overview of objectives and methods used in user tests and key insights.

	Objectives	Methods	Results and key insights
User test interviews among women and partners	<u>Usability</u> To explore how clients navigate through the conversation aid and which barriers they encounter	 Observation of clients in navigating through the different elements of the conversation aid and ask him/her to think aloud Ask specific questions to discuss participant's responses 	 The homepage was initially found to be cluttered. The pain relief options were visualized in a "cupboard" (fig. : supplementary file 1), which was not well understood After adaptations: clients and partners intuitively navigated from the homepage to the next page.
	Acceptability To explore how the conversation aid matches the information preference of clients Explore clients' attitude towards using the conversation aid, in particular what drives their potential positive or negative attitude	Ask what the clients expect from the conversation aid and reflect on the expectation at the end of the interviews.Ask whether the client would use each element, how they would use it, and what they like or dislike about each element	 All information about pain relief option on one platform. Appealing to use Needs for a "final conclusion", practical information, ability compare similar benefits and harms of options and ability to add benefits and harms.
	<u>Comprehensibility:</u> To explore how clients comprehend the purpose and content of the elements of the conversation aid	 Discuss what clients think they have to do with each element Ask specific questions about the content, e.g. could you explain in your own words how the TENS works? 	Probability information was difficult to understandToo much text
User test interviews among HCPs	<u>Usability:</u> To explore how HCPs navigate through the conversation aid and which barriers they encounter	 Observation of HCPs in navigating through the different elements of the conversation aid and ask him/her to think aloud Ask specific questions to discuss participant's responses, e.g. how would you introduce this aid to your client?; how does this element support you in explaining the options to your client? 	 Unclear how to navigate from the homepage to the next page It takes time to understand what one has to do Figures of pain relief options are unclear Positive to start with less invasive options in the cupboard; b 'shelves' give an impression of hierarchy Arrow to switch to next page to receive more information is missed
	Acceptability: To explore how the conversation aid matches the information preference of HCPs To explore HCPs' attitude towards using the conversation aid, in particular what drives their potential positive or	 Discuss what information the professional expects before starting the conversation aid and reflect on expectations at the end of the interview Evaluate pros and cons of using the aid and HCPs' opinions by asking additional specific questions, e.g. would you recommend this aid to your colleagues?; what does this aid add to current care? 	 Dragging pain relief options to the option grid is difficult Needs for a "final conclusion" Positive attitude towards provision of elaborative informatic and provision of ownership to the client. Especially useful for clients who experience difficulties with decision-making Certain elements (e.g. the value clarification exercise) take
	negative attitude <u>Comprehensibility:</u> To explore how HCPs comprehend the purpose of the elements of the conversation aid	- Discuss what HCPs think they have to do with each element, and how they would use each element in a conversation with a client.	 time to use during consultation Terminology wishes, values, norms can be vague for clients The element 'My preferences' needs an explanation: client's preferences cannot always be met. Homepage is perceived to support discussing decision topics Letting clients rank benefits and harms is perceived to give insight in client's preferences HCPs mentioned to show videos of available options during consultation/home visit HCPs mentioned a need for clients to share their questions beforehand

filling out a questionnaire). Several low HL women mentioned that a conversation aid to be used at home in advance costs time and effort and that they preferred a personal conversation.

3.3.2. Outcomes of user testing of the final prototype of the conversation aid

Table 4 provides an overview of initial results from the user test interviews, structured along the corresponding objectives and methods used. The final prototype of a conversation aid (description in Supplementary file 1) was developed and tested for usability, comprehensibility and acceptability.

In general, HCPs, women and partners showed a positive attitude towards using the conversation aid. However, all groups expressed that they were apprehensive about the time needed during consultations to use it. HCPs and clients affirmed that the conversation aid could support them in finding all necessary information about several decisions on one platform. HCPs mentioned that the conversation aid could provide ownership to clients. They found it especially useful for clients who experience difficulties during decision-making. Partners were positive about the video material that would be added and mentioned that the conversation aid was appealing to use.

As for acceptability of the conversation aid, women also expressed needs for additional practical information (e.g. information about insurance), for possibilities to add benefits and harms of options themselves, and an overview of benefit/harm information presented visually 'side by side'. Both HCPs and women expressed a need for a "final conclusion" of the conversation in the conversation aid.

In terms of comprehensibility, participants appeared to be largely able to correctly describe the purpose of the different elements of the conversation aid. However, women and partners expressed that, in general, too much text was used and some women emphasized that the probability information was difficult to understand. Also, women and partners did not fully understand the pain relief options, which were categorized in a "cupboard" (See fig. 2, supplementary file 1). The homepage was found to be cluttered; re-structuring the elements was needed to facilitate navigating from the homepage to other elements. In addition, HCPs mentioned that the element 'My preferences' needed an additional explanation, since client's preferences cannot always be met in practice during and after labor.

3.3.3. Design implications based on user testing conversation aid

Small adjustments were needed to facilitate navigating through the conversation aid. In the adapted version, decisional topics were presented in a chronological order of the pregnancy trimesters, and pain relief options were classified with a filter according to the place of birth, i.e. at home, hospital, or birth center.

Based on the feedback, we incorporated more layers to present information and we added video materials to improve comprehensibility. We also presented probability information more in line with recommended guidelines. [29] For example, we kept the denominator constant to facilitate the comparison between two or more probabilities as appropriate, and used evaluative labels to facilitate understanding of probabilities (see fig. 9, supplementary file 1). We adapted the ranking option of the 'My preferences' element (see fig. 6, supplementary file 1), where clients had to give a top 3 of pain relief options they preferred. HCPs suggested that the effectuation of preferences for pain relief may depend on whether the pain is as expected, is less than expected, or unbearable. We therefore added a functionality that allowed clients to express their preferences for pain relief options for these three different situations instead of giving a top 3 of their preferences. Also, a final element "Summary" was added to the conversation aid meet clients' and HCP's needs for a final conclusion.

3.4. Outcomes user test training

The midwifery students were positive about the presentation and role play during the training, but also expressed that they experienced difficulties to adapt their communication skills to the HL level of the actor-client during the role play. The user test findings resulted in additional adjustments in the training session's content. More information was needed about how to recognize low HL levels among clients and what strategies HCP could use to adapt (probability) information to clients' HL levels. Also, more attention was needed for the conversation aid's content and how to use it during a consultation. Therefore, additional information about what challenges clients deal with during decision-making, the teach-back method, risk communication, and case related examples (e.g. benefits and harms of pain relief options) were added to the presentation. Furthermore, the conversation aid should be available during role play, and risk communication was incorporated in the script which was used for role-play during the training.

4. Discussion and conclusion

4.1. Discussion

This study aimed to develop a Shared Decision-Making (SDM) training for healthcare professionals (HCPs) and an SDM tool (i.e. conversation aid) to support HL-sensitive SDM in maternity care. The conversation aid and training seem to suit the key objectives and needs of clients (i.e. women and partners) and HCPs, and in particular, to support HCPs in becoming acquainted with clients' general values, priorities and daily context, and help especially low HL clients to translate this into decision-making during consultations. Also, the conversation aid was adapted to the needs of low HL clients by shortening the text, adding video material and visualizations, and adhering to recommended guidelines for probability communication. However, both clients and HCPs expressed that using the conversation aid during consultations would be time-consuming. Based on the user test of the training, additional information was added about recognizing, and adapting information to, HL levels of clients to better meet HCPs needs.

4.1.1. Discussion of main findings

To better meet the needs of low HL clients, we shortened the text included in the conversation aid, added video material and visualizations, and more closely adhered to recommended guidelines on providing probability information. [29] Patients are known to be critical about available (paper or digital) decision aids, because they find them too difficult (i.e. large amount of text and small font) or confronting (i.e. very detailed information on benefits and harms of options). [30] Visualizations and educational videos can support clients with low HL to better understand information [31], but it may be a challenge for developers to create material relevant to various decisional topics.

Our co-creation sessions and user test interviews showed that clients preferred a conversation aid which could be used during encounters with their midwife to support them to become acquainted with client's values, priorities and daily context, rather than a decision support tool that could be used to prepare a consultation at home. This might be related to lower HL people's more general need to hear the opinion and experiences of their HCP explicitly in decision-making, as was shown for lower HL Dutch patients in various clinical settings. [30] Especially lower numerate people are known to also prefer experiential and anecdotal information above numerical information [32], and it might well be that lower HL/numerate clients in maternity care expect to obtain more of such information in a personal conversation with their midwife. Using a tool in a conversation rather than at home may also suit patients' need for a holistic view, i.e. exploring clinical outcomes, impact of the condition on daily life/work, emotions, coping with the condition and support from the environment, in decision-making. This holistic view is seen as an integral part of SDM by patients in other contexts as well [33], showing that low HL patients see the step of taking patients' preferences into account, or what is important in patients' life, as one of the most important steps of SDM. [30] However, a previous study where a conversation approach was developed for primary care

patients, showed that HCPs experienced difficulty to put an holistic approach into practice. [34]

Clients and professionals in our study stated that using the conversation aid during encounters would be too time consuming. Another study confirmed this finding, where low HL patients perceived too little time during conversations with their HCP in general, and for SDM in particular. [30] A systematic review on barriers and facilitators to implementing SDM from HCPs' perspective, indicated that time was the most commonly-cited barrier for implementing SDM and for using patient decision aids [35]. This makes designing decision aids that do not increase consultation time an important challenge in different medical contexts. [36] Interestingly, systematic reviews show that SDM [37] or the use of decision aids do not necessarily require more consultation time. [35].

Our study confirms the general consensus that most partners want to give meaning to their supportive role as part of the decision-making process during pregnancy and birth, but are often not included in decision-making processes. [38] Involvement of partners during pregnancy and birth may have positive outcomes for the health of the expectant parents, and their child [38], and has been shown to be influential in a number of pregnancy and birth areas, such as the place of birth. [39]. Therefore, midwives may need to engage more with expectant fathers to ensure that their contributions to decisions regarding pregnancy and birth are fully informed. [39]

Our conversation aid and training aimed to support HCPs to inform clients in an understandable manner and adapt information to clients' needs and comprehension level, yet our user test showed that participating HCPs still experienced difficulties with recognizing and adapting information to clients' HL level during the training. This was a challenge that HCPs also expressed in our previous needs assessment. [17] Therefore, more attention is given to the teach-back method in the adapted version of the training, a method that can be used universally with patients to support comprehension and recall of key information. [40]

4.1.2. Strengths and limitations

A benefit of using the conversation aid *during* encounters is that HCPs can support clients with lower digital HL skills (i.e. skills to appraise and apply health information from electronic sources to address or solve a health-related problem) if needed. However, we could not pretest the conversation aid among clients with lower digital skills, as the cocreation interviews and most user test interviews were held online due to COVID-19 restrictions. We provided support for low HL clients to participate online, yet it still could have discouraged participation of clients with lowest digital HL skills. We acknowledge the potential limitation of starting the co-creation phase with higher HL women rather than lower HL women. This was done due to pragmatic/logistical reasons. We did, however, try to overcome this potential drawback by again exploring needs for support among lower HL women. Although midwives were extensively involved in the development process, we were unable to test the final version of the conversation aid among this group of professionals. Therefore, we might have missed additional, specific needs of primary care based midwives in the final stage of the development. Their specific needs are important to address for further implementation. Furthermore, the acceptability of the training was not pilot-tested among experienced professionals. Experienced professionals could have added suggestions to improve the training, for example focusing on practical barriers.

4.2. Innovation

To the best of our knowledge, only few studies have developed and evaluated decision aids targeting low HL clients, [9] or used co-creation to develop SDM training and decision support tools in maternity care. [41] Furthermore, this study adds to the scarce literature on partners' needs regarding SDM. [38] One unique aspect was the attention to partners' involvement in decision-making, especially by including partners in the co-creation sessions and user tests. This is important from a quality of care perspective, for example because partner involvement is important to support collaboration between parents and HCP, to make informed decisions, and to advocate for both parents' needs.

The developed SDM training and conversation aid have potential to support HCPs and clients in HL-sensitive SDM. Clients' and HCPs' had a positive attitude towards using the conversation aid, yet also considered the time needed to complete it with clients to be a barrier. Time constraints will remain a barrier for implementation as long as SDM and using decision aids are perceived as an additional form of care for which additional time needs to be found. [42] More research is needed to identify solutions for the barriers that HCPs and clients perceive regarding acceptability and usability of the newly developed training and conversation aid in practice, and how decision aids can be used to, for example, structure conversations in order to provide HL-sensitive SDM within the time HCPs have. Finally, developers could adopt a universal-based approach in designing digital tools to provide accessibility to patients with varying digital HL levels. Smith and Magnani [43], for example, proposed as a first step in their "Digital Universal Precautions" to involve a multidisciplinary team. Including stakeholders in the development process who have knowledge of, and influence on, organizational level is also recommended for successful implementation of SDM interventions. [41] This approach including a user-centered design is known to enhance patient decision aid's quality and acceptability, and to improve the likelihood of successful implementation. [32]

5. Conclusions

HCPs and clients had a positive attitude towards using the conversation aid, however they also perceived that using the conversation aid during consultations would be time consuming. Future research is needed to evaluate how the co-created strategies can be implemented in a real-life setting within the time HCPs and clients have in consultations.

Ethics approval and consent to participate

This study was approved by The Medical Ethics Committee of the Academic Medical Center of the University of Amsterdam in 2018 and conducted in accordance to the relevant guidelines and regulations. We guaranteed the anonymity of participants and ensured that written informed consent was obtained prior to the survey and observations.

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CRediT authorship contribution statement

Laxsini Murugesu: Data curation, Formal analysis, Project administration, Writing – original draft, Writing – review & editing. Mirjam P. Fransen: Conceptualization, Formal analysis, Funding acquisition, Methodology, Supervision, Writing – review & editing. Danielle R.M. Timmermans: Formal analysis, Supervision, Writing – review & editing. Arwen H. Pieterse: Writing – review & editing. Ellen M.A. Smets: Formal analysis, Supervision, Writing – review & editing. Olga C. Damman: Conceptualization, Formal analysis, Funding acquisition, Methodology, Supervision, Writing – review & editing.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests.

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Data availability

The data presented in this study are available on request from the corresponding author, provided that approval from the research group is obtained and agreement is made on data security, data transfer, period of data availability, and possible use of data (for commercial ends), costs for use of data and methodology. The data are not publicly available due to privacy of participants.

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Appendix A. Supplementary data

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