

ORIGINAL ARTICLE

Behavior change training for pregnant women's communication during birth: A randomized controlled trial

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Abstract

Applying health psychological theories can improve communication interventions to empower pregnant women and ensure safe births. The aim was to test a short digital communication intervention based on the health action process approach. A randomized-controlled trial was conducted with pregnant women at two German university hospitals. The intervention group ($N_{T1} = 225$; $N_{T2} = 142$) received a 2.5 h online training focusing on communication planning, self-efficacy and communicating personal needs and preferences under difficult circumstances. This group was compared with a passive control group ($N_{T1} = 199$; $N_{T2} = 144$). Data from the $N = 286$ women with complete datasets were used for multilevel analyses. Data from all recruited $N = 424$ women were used for intention-to-treat analyses with multiple imputation. Both groups improved regarding communication behavior, quality of birth, action planning, coping planning and coping self-efficacy after birth, which was more pronounced in the intervention group. The intention-to-treat analyses confirmed the higher improvement for communication behavior, perceived

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quality of birth and coping planning. The intervention was related to improvements in pregnant women's communication behavior and quality of birth. Hence, future research and practice should apply and evaluate health psychological theories when targeting communication and empowerment.

KEYWORDS

behavior change, health action process approach, obstetrics, patient empowerment, patient safety, patient-provider communication

INTRODUCTION

In the last decades, the focus on quality in healthcare has shifted towards patient-centered care, meaning to provide care “that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions” (Wolfe, 2001). Because every advance in healthcare means that stakeholders have to change their behavior, implementation sciences should regard a behavioral perspective. The emphasis on patient-centered care means that both healthcare workers and patients have to adapt (Moore et al., 2017; Patey et al., 2022). However, changing behavior can be challenging or even unsuccessful if interventions are not based on theory and evidence. Applying behavioral theories can facilitate behavior change by focusing on important determinants and processes of behavior change (Patey et al., 2018).

A crucial requisite of patient-centered care is good patient-provider communication. However, many studies and communication theories have neglected the multiple components that are needed to create sustainable behavior change (Michie et al., 2018). Individual determinants are crucial to describe how safe communication is developed, performed and maintained. Additionally, research has focused on communication as a part of teamwork, neglecting the patient perspective. This is especially true for obstetric care. A recent review by Lippke et al. (2021) on the effectiveness of obstetric communication interventions revealed that only 3 out of 71 studies (4.2%) targeted pregnant women's communication skills in their interventions (Bajens et al., 2018; Franzon et al., 2019; Roter et al., 2015). In their PRENACEL trial, Franzon et al. (2019) found positive effects of a text message and interview program in a randomized parallel trial on preparedness for childbirth and postnatal care. Roter et al. (2015) offered a computer-based communication intervention to a randomized group of pregnant women and found that it helped women to enclose more information. However, this made clinicians communicate less medical information, and women had lower satisfaction scores. In contrast, Bajens et al. (2018) did not find positive effects of a 4-min educational video aiming to facilitate shared-decision making in their pilot study with a pre-post design.

The fact that only three studies with varying methodology, focus and quality exist indicates the need for high-quality research on communication interventions for pregnant women. Effective communication in obstetrics determines both objective patient safety outcomes and the degree of self-determination and patient satisfaction (Iverson &

Heffner, 2011). Although avoidable patient harm is rather uncommon with around 2%–3% of all patients experiencing so-called “preventable adverse events” (pAE; Aibar et al., 2015), obstetric or perinatal pAE have grave consequences for mothers, newborns and the healthcare system (Pettker & Grobman, 2015). Additionally, a perceived negative interaction with healthcare providers can affect mothers’ physical and mental health in the long-term. Even if both the mother and newborn are physically safe after birth, negative birth experiences, such as feeling unsafe, can negatively impact family adjustment such as bonding and breastfeeding (Simpson et al., 2018). Approximately 12% of all women giving birth experience some post-traumatic stress symptoms with 4.7% needing treatment due to birth-related post-traumatic stress disorder (Heyne et al., 2022). These symptoms are caused not only by a poor quality of provider communication but also by a perceived lack of the women’s own communication regarding the uptake or refusal of interventions (Hollander et al., 2017; Simpson & Catling, 2016). Thus, communication empowerment of pregnant women is important not only in pathological births but also in preventing negative experiences in every birth and reducing pathological births such as unnecessary caesarian sections. It has been shown that women are more likely to have a caesarian section when they display higher levels of fear and a lack of confidence (Zhao & Chen, 2013). Furthermore, Abenhaim et al. (2007) have linked a better rapport and communication with lower caesarian section rates. Although the World Health Organization (WHO) suggests caesarian section rates of 5%–15%, the worldwide mean is much higher with approximately 45% (Vega-Soto et al., 2015).

To summarize, there is a need to extend the existing literature on communication interventions for pregnant women and a call to add a behavioral perspective. There are several theories that have proven useful in implementing new policies and perspectives, including learning theories, motivational theories and theories that focus on the action aspect of behavior (Patey et al., 2018). One of the latter theories is the Health Action Process Approach, which focuses on bridging the intention-behavior gap (HAPA; Schwarzer & Hamilton, 2020). The HAPA is a phase-specific behavior change model that assumes a motivational and a volitional phase. Applied to pregnant women’s communication behavior, risk perceptions set the stage for change and outcome expectancies (i.e. expecting that one’s own safe communication can positively impact birth experiences) directly influence the intention to communicate well. Afterwards, individuals enter the volitional stage. In this case, pregnant women need to actively prepare for communication during childbirth and anticipate how they can adapt their plans in difficult situations, for example, if a need for a medical procedure occurs (“coping planning”) to overcome the intention-behavior gap. Throughout the entire process, different forms of self-efficacy are necessary to build, carry out, and maintain the intended behavior. The HAPA offers different leverage points indicating how behavior change techniques can be used. It has been validated in a variety of contexts (Schwarzer & Hamilton, 2020), but its applicability to patients’ communication, especially pregnant women, has yet to be investigated.

Hence, the main goal of this research was to apply the HAPA to safe communication in obstetrics from a pregnant woman’s perspective and develop a communication intervention targeting HAPA variables. In more detail, we hypothesized that the communication training would have a positive effect on communication, outcome expectancies/perceptions of birth outcomes, perceived risks for adverse events, and social-cognitive variables (coping self-efficacy, action, and coping planning).

METHODS

Study information and ethical approval

This research is part of the project “TeamBaby – Safe, digitally supported communication in obstetrics and gynecology” ([ClinicalTrials.gov](https://clinicaltrials.gov) Identifier: NCT03855735), which aims to enhance patient safety and communication in obstetrics. Outcome measures include questionnaire data regarding psychological determinants and perceived communication, which are presented in this manuscript. Other research questions such as the individual transfer and mechanisms were investigated with qualitative interviews (Schmiedhofer et al., 2022). Objective clinical outcome measures will be analyzed separately to answer the research question whether the intervention could improve objective birth trajectories. This research follows the CONSORT guideline for reporting parallel group randomized trials. Although a full randomization was planned, $N = 64$ (22.4%) of all participants had to be allocated, so that only a partial randomization could be realized (see “Participants and Procedure” section for details).

Participants and procedure

The study took place at two German university hospitals which perform 2800 to 3200 deliveries annually, around 50% of which are medium-to-high risk. At each hospital, internal project staff (a study nurse and a research associate) were responsible for the recruitment process. Expectant mothers and their support persons (mostly partners) were eligible if they were German speakers, of legal age, and planning to give birth at one of the two hospitals. Potential participants were informed about the research project in several recruiting channels. Information materials such as flyers, posters, and registration forms with a mail-in box were distributed in the hospital at significant points of contact (e.g. pregnancy outpatient clinic, waiting rooms, wards, corridors and lifts, and information boards) and distributed to resident gynecologists, midwives, pregnancy counseling services, pharmacies, and relevant baby stores in the catchment area of the clinics. Further, the clinical staff affiliated with the project informed the potential participants about the project and training during pre-birth consultations and online information events. The project was promoted on the hospitals' homepages, social media, and in regular press releases. In one of the hospitals, all women who registered for birth were informed about the project. In the other hospital, there was no registration prior to birth.

The participants received detailed study information together with the baseline questionnaires via e-mail. They gave their informed consent at the beginning of the online questionnaire by explicitly clicking on a “yes” button. Without the indication of informed consent, the questionnaire could not be completed, and the participants were considered dropouts. After finishing the questionnaires, the participants received the information whether they had been assigned to the intervention or control group. The intervention group received further information and the invitation for their training session 7 days before the training. After giving birth, participants filled in the post-intervention questionnaire (T2), which was matched to the baseline data via a unique code generated by the participants. There were occasional reminders to fill in the questionnaires via e-mail and/or telephone.

Data were collected from June 2020 to October 2021. Of the $N = 492$ expectant mothers who registered for participation, $N = 424$ provided baseline measures (T1), and $N = 288$ participants completed the post-intervention questionnaire (T2). Of those, $N = 286$ could be matched

to the baseline measures based on the study codes. The other two were excluded from further analyses. Other reasons for study attrition/dropout ($N = 138$) included delivery of the baby at a different hospital by choice (e.g. choosing a birth center over a hospital or avoiding strict COVID-19 containment measures such as not being able to bring a partner; $N = 97$, 70.3%), no T2 questionnaire after more than four reminders ($N = 27$, 19.6%), forced delivery at another hospital due to capacity limits (e.g. women in labor had to be transferred to other hospitals in case of low risk, $N = 5$, 3.6%), pre-term delivery before participating in the training in the intervention group ($N = 4$, 2.9%), critical health status after delivery (likely due to prior high-risk pregnancy and birth; $N = 4$, 2.9%), and a bad experience during delivery ($N = 1$, 0.7%).

Although a full randomization was scheduled, not all patients could be allocated as planned because some expectant mothers were unable to attend the next training session due to their imminent delivery date. Hence, $N = 52$ (36.1%) out of $N = 144$ women who provided data after birth in the control group were allocated and not randomized. Additionally, the initial recruitment was slow so that all interested women were assigned to the intervention group during the recruitment period for the first two out of 20 training sessions to ensure the possibility for group discussion and learning. Thus, $N = 12$ (8.4%) out of $N = 144$ women who provided data after birth in the intervention group were allocated instead of randomized. Accordingly, a full randomization was performed by the study personnel at the hospitals with prepared closed envelopes with a 3:2 ratio for $N = 222$ (77.6%) of all participants 7 to 10 days prior to the next training session, and $N = 64$ (22.4%) of all participants were re-allocated. All healthcare workers were blinded as to who of the women giving birth took part in the study unless a woman explicitly mentioned it during their stay in the delivery rooms. Figure 1 includes a flow-chart on the trial design.

Intervention

Two collaborating companies for communication trainings targeting patient safety (run by midwives and an anesthesiologist) developed and conducted the TeamBaby safe communication trainings for expectant mothers in close cooperation with the project team consisting of health psychologists, public health experts, sociologists, and obstetric healthcare professionals. Previous face-to-face trainings for healthcare workers were adapted to pregnant women and their partners. To comply with the restrictions of the COVID-19 pandemic, the practice sessions were switched to 2.5 h interactive and patient-centered online sessions. The budget was sufficient for 20 training sessions from June 2020 to August 2021. In preparation for the training, the participants received a self-reflection questionnaire regarding needs and preferences for the birth including support persons, potential anesthetics, atmosphere, mode of delivery, and bonding (see Data S1).

The HAPA was used to guide the training development. Main behavioral determinants from the motivational phase were (1) risk perceptions and outcome expectancies (create an awareness about patient safety risks caused by inadequate communication behavior while emphasizing that an effective communication behavior can reduce risks) and (2) intention (motivate participants to engage in behavior change). For the volitional phase, factors included (1) coping self-efficacy (provide instructions to follow and create positive experiences) and (2) coping planning (use specific strategies to create a plan for communication during childbirth, especially under difficult circumstances). Appropriate Behavior Change Techniques (BCT) were chosen based on the BCT taxonomy by Michie et al. (2013).

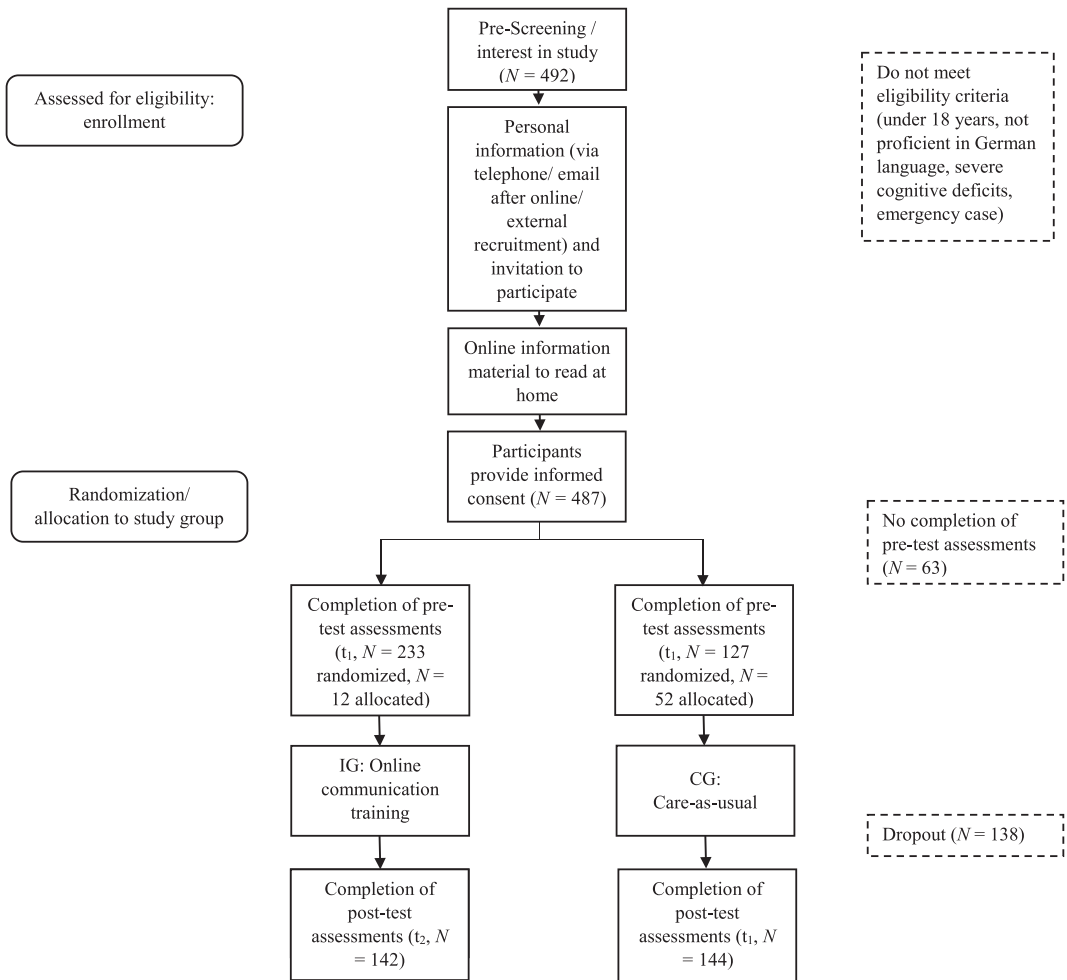


FIGURE 1 Flow chart and study design. Trial design. Participants (pregnant women/obstetric patients) were initially identified and screened for eligibility during consultation in study hospitals or via telephone after online recruitment. If eligible, participants were invited to take part in the study, consent and providing their e-mail address. Participants were randomized or allocated to either the intervention group (IG, online communication training) or the control group (CG) before receiving an online module including written informed consent, followed by the online assessment of pre-tests. Participants in the intervention group completed the online communication training. All patients completed post-tests after giving birth.

Accordingly, the online training session consisted of an introduction round in which participants were asked what their “ideal” birth would be like and whether they had prior experiences so that the trainers could understand individual needs and potential communication approaches (Goal setting regarding outcome [BCT 1.3] and Commitment [BCT 1.9]). This was followed by an intervention on perspective taking (“empathy maps”) in which the participants were asked to consecutively take the perspective of a midwife, a doctor, a pregnant woman and her partner. To deepen mutual understanding, the participants were asked to answer the questions: “What are this person’s tasks/thoughts/needs/fears?” (monitoring of emotional consequences [BCT 5.4], goal setting (behavior) [BCT1.1], commitment [BCT1.9], and social support

[BCT3]). Afterwards, participants practiced communication competencies with given examples from obstetric care (action planning [BCT 1.4], discrepancy between current behavior and goal [BCT 1.6], and instruction on how to perform the behavior [BCT 4.1]). The communication techniques “speaking up” to adequately voice own needs or concerns (action planning [BCT 1.4], commitment [BCT 1.9], and information about health consequences [BCT 5.1]) and “closed-loop communication” to facilitate information flow and correct understanding by repeating information given by healthcare workers (feedback and monitoring [BCT 2] and prompts/cues [BCT 7.1]). Conclusively, participants were invited to develop an adequate strategy, plan and practice their communication behavior regarding their individual needs (action planning [BCT 1.4], behavioral contract [BCT 1.8], and commitment [BCT 1.9]). Data S1 provides an overview of the training exercises, the associated behavioral determinants based on the HAPA and the BCT in Table A4 and the preparatory questionnaire.

Measures

Rider and Keefer's (2006) communication competencies were translated into items to measure communication behavior. For the pre-specified determinants derived from the HAPA, items and scales were based on previously published, validated scales (Gholami et al., 2016). These were adapted and discussed among the project team. An English translation of the final questionnaire is displayed in Data S1. Finally, communication behavior was measured with 7 items (Cronbach's $\alpha = .67$ at T1 and $.83$ at T2). Outcome expectancies (at baseline, T1) and perceptions of outcomes (at T2) were measured with 3 items (Cronbach's $\alpha = .81$ at T1 and $.82$ at T2). Action planning, coping planning, and coping self-efficacy were measured as single-item scales at both timepoints. All items were measured on a 6-point Likert scale (1 = *Not at all* to 6 = *Absolutely*). For perceived patient safety risks, the “Perceptions of Preventable Adverse Events Assessment Tool” (PPAEAT; Keller et al., 2021) was shortened to a single scale with 9 items and adapted to the pregnant women's perspective (Cronbach's $\alpha = .84$ at T1 and $.86$ at T2). Items were measured on a 6-point Likert scale at T2 (1 = *Not at all* to 6 = *Absolutely*), and on a 4-point Likert scale at T1 (1 = *Not at all* to 6 = *Absolutely*). For comparability, values at T1 were recoded for the analyses using the formula “ $Y = (B - A) * (x - a) / (b - a) + A$ ” with the old minimum a, new minimum A, old maximum b, and new maximum B (IBM Statistics, 2020).

Categorical questions were applied and summed up to more frequent categories. They include age (1 = “younger than 20 years of age,” 2 = “20–29 years,” 3 = “30–39 years,” 4 = “40–49 years”), number of pregnancies, pregnancy with one or more children (1 = “single child,” 2 = “twins,” 3 = “triplets or more”), education (1 = “middle school degree or lower,” 2 = “high school diploma,” 3 = “vocational training,” 4 = “university degree”), marital status (1 = “single,” 2 = “in a relationship,” 3 = “married,” 4 = “divorced/separated”), nationality (1 = “German,” 2 = “Other”) and mode of delivery after birth (1 = “spontaneous,” 2 = “spontaneous after expected C-section,” 3 = “planned C-section,” 4 = “unplanned C-section,” 5 = “vacuum or forceps”).

Data analysis

Participants who dropped out were compared with participants who provided T2 data using χ^2 -tests for categorical socio-demographic data and independent *t*-tests for T1 scales using SPSS version 28 (see Table A1 in Data S1).

Means and standard deviations for self-reported communication behavior, perceived patient safety risks, birth outcomes, and the social-cognitive variables (coping self-efficacy, action, and coping planning) are reported. Training effects per protocol for these variables were analyzed using multiple hierarchical-linear models (HLM) with random coefficients in RStudio version 4.1.2 (RStudio Team, 2020). The sample size of 286 subjects at level 2 is larger than usually recommended (Snijders, 2005). The data were restructured to a long format with the *gather*-function from the package *tidyr* after filtering out the missings. The HLM were fitted with the *lme*-function from the *nlme*-package. Timepoints were added on level 1 and subjects on level 2. Fixed effects were modeled for time, group, and the binary-coded control variable “hospital” on level 2 as well as the Time*Group interaction. The random intercept and slope for individual trajectories were added. For the per protocol analyses with the $N = 286$ pregnant women who provided both baseline data (T1) and data after birth (T2), missing data were 2.5%.

To verify the analyses using an intention-to-treat (ITT) approach, the same models were fitted to multiply imputed datasets using the total sample of $N = 424$ pregnant women who provided baseline data before pooling results. Results are displayed below and summarized in Table A3 in Data S1. The Multiple Imputation by Chained Equations (MICE) was chosen as imputation method. First, the set of predictors was specified in the predictor matrix. In the analysis, the subject/patient number was removed from the predictor set. The default value for the predictors was set to imputation models with fixed effects as has been recommended in the literature (van Buuren & Groothuis-Oudshoorn, 2011). Next, binary-coded, ordered, and unordered categorical variables were defined as factors and added to the method matrix using “*polr*,” “*logreg*,” and “*polyreg*” prediction methods, respectively (otherwise “*pmm*” is selected by default). To apply the MICE algorithm (function *mice* in R), the number of imputed datasets to be computed (variable *m* in *mice*) was set to 10 according to prominent guidelines (Rubin, 1987). More recently, Bodner (2008) has questioned this guideline, considering the effects of the fraction of missing information F , among others. For the purpose of the present study and with $F = 0.12$ over all variables, it turns out that no more than $m = 10$ is needed. Furthermore, to assure a proper convergence of the algorithm, the maximum number of iterations for each dataset (variable *maxit* in *mice*) was chosen to be 20. Finally, and without loss of generality, the seed parameter was set to 123. R codes for both the per protocol and ITT analyses are displayed in Data S1.

RESULTS

Participants

$N = 424$ pregnant women completed baseline questionnaires in the 16th to 41st week of pregnancy ($M = 34.32$, $SD = 3.61$). $N = 228$ (53.8%) came from the first hospital and $N = 196$ (46.2%) from the second clinic. A majority ($N = 404$, 95.3%) were pregnant with a single child for the first ($N = 257$, 60.6%) or second time ($N = 121$, 28.5%) and married or in a relationship ($N = 409$, 96.5%). Additionally, most pregnant women were German ($N = 367$, 86.6%) and held a university degree ($N = 326$, 76.9%). $N = 225$ (53.1%) women were randomly assigned to the intervention group and $N = 199$ (46.9%) to the control group. In the intervention group, $N = 220$ (97.8%) pregnant women received the communication training, and $N = 142$ (63.1%) provided data after giving birth in one of the study hospitals. These women received the intervention 2 to 184 days before the delivery ($M = 34.44$, $SD = 29.49$). In the control group,

$N = 144$ (72.4%) pregnant women provided data after birth. Table 1 provides a detailed overview of these pregnant women's socio-demographic characteristics.

Participants who dropped out from the intervention group did not differ from participants who completed the intervention and provided T2 data regarding their socio-demographic data, $\chi^2(1-3) = 0.19$ to 3.48 , $p = .084$ to $.665$, the exception being their outcome expectancies at baseline, $t(221) = -1.76$, $p = .040$. In the control group, participants who dropped out also did not differ from those who completed the T2 questionnaires regarding their socio-demographic data, $\chi^2(1-3) = 0.65$ to 5.53 , $p = .170$ to $.682$. There were baseline differences regarding coping self-efficacy, $t(194) = -2.08$, $p = .020$, and coping planning, $t(194) = -1.71$, $p = .045$. Table A1 in Data S1 provides a detailed overview of statistics regarding drop-out analyses separated by groups.

Training evaluation

Per protocol analyses

Figure 2 displays means and standard deviations for communication behavior, perceived patient safety risks, and the social-cognitive variables for all pregnant women who provided T2 data separated by group. In both groups, all study variables except for perceived patient safety risks showed a descriptive improvement over time with small advantages for the intervention group. Perceived patient safety risks were descriptively slightly lower after birth in the intervention group and slightly higher after birth in the control group when compared with the group's baseline at T1.

For communication behavior, the HLM showed significant differences between the intervention and the control group, $b_2 = 0.16$, 95% CI [0.01; 0.32], $t(271) = 2.05$, $p = .041$. Both groups improved over time (T1 vs. T2, $b_3 = 0.81$, 95% CI [0.69; 0.94], $t(272) = 12.62$, $p < .001$) with a more pronounced improvement in the intervention group as indicated by a negative interaction between the group and the changes over time, $b_4 = -0.24$, 95% CI [-0.42; -0.06], $t(272) = -2.68$, $p = .008$. Regarding perceived patient safety risks, the HLM showed that participants from the intervention group perceived less patient safety risks after giving birth, as indicated by a positive Time*Group interaction, $b_4 = 0.30$, 95% CI [0.02; 0.58], $t(238) = 2.10$, $p = .037$. For outcome expectancies/perceived birth outcomes, the HLM showed significant improvements between the two timepoints, $b_3 = 0.56$, 95% CI [0.39; 0.73], $t(274) = 6.52$, $p < .001$, with a higher improvement in the intervention group, $b_4 = -0.44$, 95% CI [-0.68; -0.201], $t(274) = -3.62$, $p < .001$. For the social-cognitive variables, patterns were similar. Regarding coping self-efficacy, the HLM showed that T2 levels were higher than the initial levels, $b_3 = 1.11$, 95% CI [0.86; 1.35], $t(279) = 9.00$, $p < .001$, with a more pronounced advantage for the intervention group after the communication intervention, $b_4 = -0.40$, 95% CI [-0.74; -0.06], $t(279) = -2.29$, $p = .023$. Regarding action planning, the groups differed significantly when aggregated over timepoints, $b_2 = 0.32$, 95% CI [0.06; 0.58], $t(277) = 2.39$, $p = .018$. Additionally, both groups improved over time, $b_3 = 1.09$, 95% CI [0.82; 1.36], $t(278) = 8.04$, $p < .001$, with the intervention group showing a greater improvement, $b_4 = -0.59$, 95% CI [-0.97; -0.21], $t(278) = -3.05$, $p = .003$. Finally, the HLM showed significant differences for coping planning between the hospitals, $b_1 = -0.20$, 95% CI [-0.40; -0.01], $t(274) = -1.99$, $p = .047$, the two groups, $b_2 = 0.32$, 95% CI [0.07; 0.57], $t(274) = 2.49$, $p = .013$, as well as between timepoints, $b_3 = 1.06$, 95% CI [0.79; 1.32], $t(275) = 7.81$, $p < .001$. The increase in

TABLE 1 Socio-demographic characteristics of the pregnant women who provided data after giving birth

		IG (N = 142)	CG (N = 144)	Dropped out^a (N = 138)
Hospital	1	76 (53.5%)	72 (50%)	80 (58%)
	2	66 (46.5%)	72 (50%)	58 (42%)
	Not reported	0 (0%)	0 (0%)	0 (0%)
Nationality	German	122 (85.9%)	122 (84.7%)	123 (89.1%)
	Other	20 (14.1%)	18 (12.5%)	13 (9.4%)
	Not reported	0 (0%)	4 (2.8%)	2 (1.4%)
Age	Younger than 20	0 (0%)	0 (0%)	1 (0.7%)
	20–29	14 (9.9%)	19 (13.2%)	18 (13%)
	30–39	119 (83.8%)	107 (74.3%)	108 (78.3%)
	40–49	9 (6.3%)	14 (9.7%)	9 (6.5%)
	Not reported	0 (0%)	4 (2.8%)	2 (1.4%)
Pregnancy characteristics	Single child	137 (96.5%)	133 (92.4%)	134 (97.1%)
	Twins or more	5 (3.5%)	7 (4.9%)	2 (1.4%)
	Not reported	0 (0%)	4 (2.8%)	2 (1.4%)
Number of prior pregnancies	1	85 (59.9%)	80 (55.6%)	92 (66.7%)
	2	44 (31%)	45 (31.3%)	32 (23.2%)
	3	11 (7.7%)	8 (5.6%)	7 (5.1%)
	4	2 (1.4%)	7 (4.9%)	3 (2.2%)
	Not reported	0 (0%)	4 (2.8%)	4 (2.9%)
Mode of delivery	Spontaneous	77 (54.2%)	80 (55.6%)	
	Spontaneous after expected C-section	2 (1.4%)	2 (1.4%)	
	Planned C-section	7 (4.9%)	14 (9.7%)	
	Unplanned C-section	31 (21.8%)	28 (19.4%)	
	Birth using vacuum or forceps	18 (12.7%)	12 (8.3%)	
	Not reported	7 (4.9%)	8 (5.6%)	
Marital status	Single	2 (1.4%)	3 (2.1%)	3 (2.2%)
	In a relationship	34 (23.9%)	27 (18.8%)	39 (28.3%)
	Married	106 (74.6%)	109 (75.7%)	94 (68.1%)
	Divorced/separated	0 (0%)	1 (0.7%)	0 (0%)
	Not reported	0 (0%)	4 (2.8%)	2 (1.4%)
Education	Middle school diploma or lower	2 (1.4%)	3 (2.1%)	4 (2.9%)
	Highschool diploma	7 (4.9%)	6 (4.2%)	9 (6.5%)
	Vocational training	19 (13.4%)	27 (18.8%)	14 (10.1%)
	University degree	113 (79.6%)	104 (72.2%)	109 (79%)
	Not reported	1 (0.7%)	4 (2.8%)	2 (1.4%)

^aDropout was due to choosing another hospital for delivery, not providing data after giving birth, delivering the baby before being able to join the training, or a critical health status after birth. There is no information on mode on delivery for women who dropped out of the study.

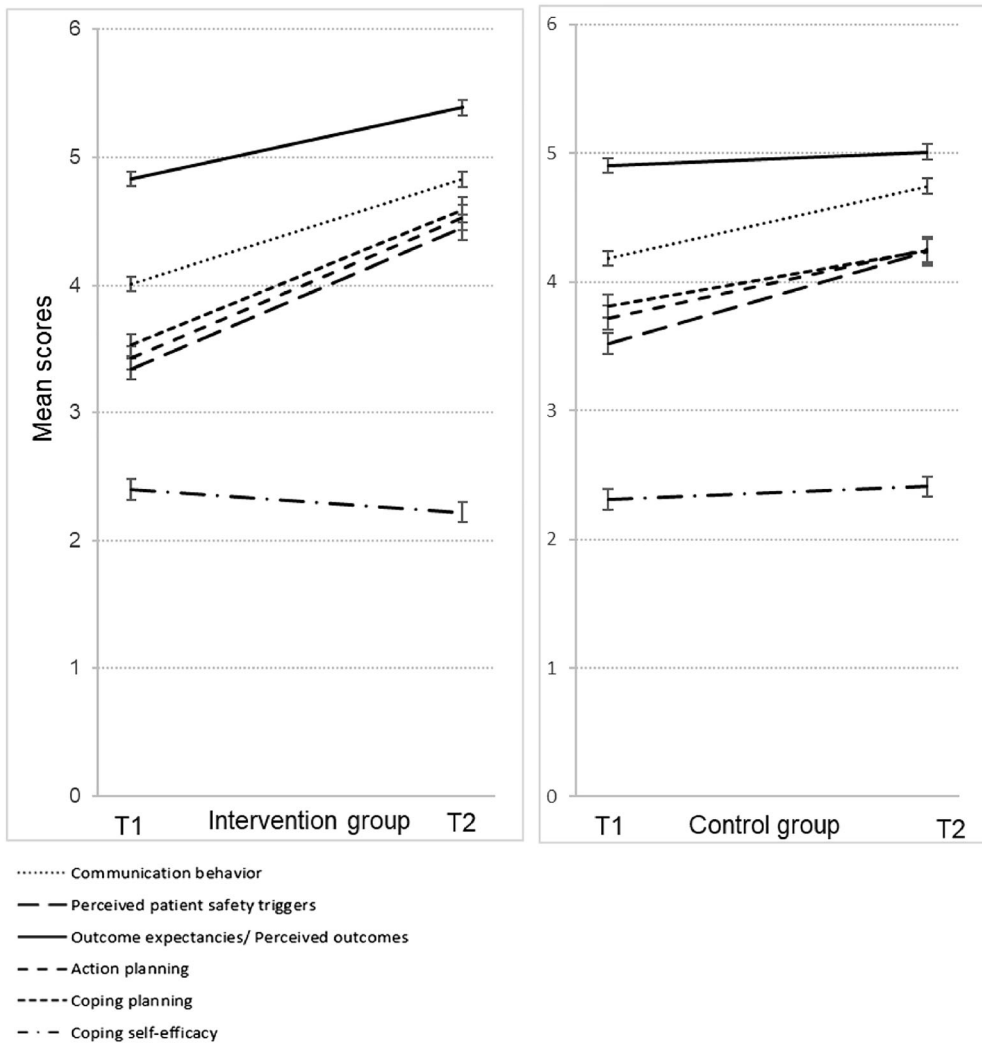


FIGURE 2 Means and standard errors at T1 and T2 according to group. Note: Only participants who provided both T1 and T2 data are displayed in this figure.

coping planning was higher in the intervention group, $b_4 = -0.67$, 95% CI $[-1.05; -0.29]$, $t(275) = -3.48$, $p < .001$. Table A2 in Data S1 summarizes all statistics for models without imputations.

ITT analyses

The multilevel analyses with multiply imputed datasets showed mostly the same pattern of results with some differences. For communication behavior, there were differences between the groups when aggregating timepoints, $b_2 = 0.14$, 95% CI $[0.01; 0.27]$, $t(837.39) = 2.17$, $p = .035$, and both groups improved over time $b_3 = 0.64$, 95% CI $[0.44; 0.83]$, $t(20.95) = 6.80$, $p < .001$. This improvement was stronger in the intervention group, $b_4 = -0.19$, 95% CI $[-0.38; -0.01]$, t

(128.80) = -2.05 , $p = .043$. Regarding perceived patient safety risks, the analysis did not show any difference between groups regarding the change over time as indicated by the non-significant Time*Group interaction, $b_4 = 0.20$, 95% CI $[-0.07; 0.47]$, $t(250.06) = 1.46$, $p = .146$. For outcome expectancies/perceived birth outcomes, the HLM did not show differences between timepoints when groups were aggregated, $b_3 = 0.10$, 95% CI $[-0.23; 0.43]$, $t(17.47) = 0.61$, $p = .547$, but the intervention group showed a more pronounced improvement than the control group, $b_4 = -0.31$, 95% CI $[-0.61; -0.01]$, $t(92.03) = -2.04$, $p = .044$. For the social-cognitive variables, patterns differed slightly from the analyses without imputation. Regarding coping self-efficacy, the HLM with multiple imputed datasets only that both groups had better self-efficacy at T2, $b_3 = 0.62$, 95% CI $[0.18; 1.06]$, $t(16.50) = 2.99$, $p = .008$, but the increase did not differ between groups, $b_4 = -0.13$, 95% CI $[-0.53; 0.27]$, $t(66.55) = -0.64$, $p = .525$. With regard to action planning, the groups differed when timepoints were aggregated, $b_2 = 0.27$, 95% CI $[0.06; 0.48]$, $t(836.73) = 2.47$, $p = .014$, and there were higher levels in both groups after giving birth, $b_3 = 0.66$, 95% CI $[0.28; 1.05]$, $t(23.21) = 3.56$, $p = .002$, but no differences in changes between the timepoints and groups (i.e. the Group*Time interaction effect), $b_4 = -0.33$, 95% CI $[-0.71; 0.05]$, $t(150.75) = -1.70$, $p = .091$ were found. Participants reported different levels of action planning between hospitals, $b_1 = -0.24$, 95% CI $[-0.43; -0.05]$, $t(332.76) = -2.52$, $p = .012$. Lastly, the analysis for coping planning still showed significant differences for all fixed effects: participants differed between hospitals, $b_1 = -0.26$, 95% CI $[-0.45; -0.06]$, $t(160.11) = -2.65$, $p = .008$ and study groups, $b_2 = 0.23$, 95% CI $[0.03; 0.44]$, $t(835.68) = 2.24$, $p = .025$. Although both groups improved over time, $b_3 = 0.68$, 95% CI $[0.34; 1.02]$, $t(32.51) = 7-81$, $p < .001$, this was more pronounced in the intervention group, $b_4 = -0.37$, 95% CI $[-0.74; -0.01]$, $t(230.38) = -1.99$, $p = .047$. Table A3 in Data S1 summarizes the fixed effects of the HLM with imputed datasets.

DISCUSSION

The results presented in this paper reflect the questionnaire data regarding health psychological determinants of safe communication behavior. Within the scope of the TeamBaby project, the routine clinical data concerning the participants' births are currently being analyzed to examine the research question whether a communication intervention for pregnant women can reduce pAE. To understand the experiences in the hospitals after training and examine the individual training mechanisms, qualitative interviews with a subset of the women and different research questions were published elsewhere (Schmiedhofer et al., 2022). This current research aimed to apply the Health Action Process Approach (HAPA; Schwarzer & Hamilton, 2020) as a theoretical basis for an online communication training targeting pregnant women to enhance their communication during childbirth. The training targeted communication behavior, perceived safety, and the perception of birth outcomes along with coping self-efficacy, and action and coping planning as social-cognitive variables derived from the HAPA. In all outcome variables except for perceived patient safety, both groups improved after giving birth compared with the baseline measure. The per protocol analyses showed better outcomes in the intervention group compared with the control group for all variables. ITT analyses with multiple imputation confirmed the results for communication behavior, perceived birth outcomes and coping planning, but not for perceived safety, coping self-efficacy, or action planning.

Discussion of the main findings

Our findings regarding the improvement in communication behavior are in line with the positive findings of a prior study by Franzon et al. (2019), who also applied a digital approach to enhance information seeking in pregnant women. However, they used a text-messaging program with four messages per week to help antenatal preparation. Our approach was to offer a 2.5 h online training workshop after a detailed questionnaire to actively engage women in voicing their needs and concerns. Our outcome measures focused on social-cognitive variables derived from a behavior change theory. According theories were useful in explaining mechanisms and informing healthcare interventions before (Martin et al., 2010). Nevertheless, “classic” behavior change theories might not sufficiently consider the intention-behavior gap. The HAPA presents an extension of classical theories by proposing behavioral factors such as planning and self-efficacy after the formation of intention (Sniehotta et al., 2005). In our initial per protocol analyses, there were improvements in these factors after the communication training. However, the ITT analyses only showed the group-specific improvement in coping self-efficacy but no evidence for the role of planning in taking action.

In the initial analyses, we found that the intervention group benefitted from the intervention regarding perceived patient safety when compared with the control group, yet the ITT analyses did not find this interaction. However, the target of the intervention was to empower patients to get involved in shared decision-making by improving behavioral factors derived from the HAPA. Thus, this study focused on communication behavior and subjective birth outcomes. Women in the intervention group reported better outcomes regarding the atmosphere, the respect of their needs, and consideration of all necessary information. These results match Franzon et al. (2019), who found positive effects of their intervention regarding the perception of being prepared for birth but not for medical outcomes. Their study is, to our knowledge, the only one to evaluate birth outcomes after training pregnant women. However, the WHO (2021) has encouraged researchers, policy makers, and practitioners to specifically target patient safety. Furthermore, the WHO has recommended policy makers and practitioners to work on lowering the rate of caesarean sections worldwide (Vega-Soto et al., 2015). In the descriptive results, we found that the women in the intervention group reported lower rates of planned caesarean sections, which might have had to do with the communication training increasing their confidence to choose a natural birth. However, because the control group was not fully randomized and there was no investigation of the concrete mechanisms, other factors or simply a coincidence might account for this finding. Consequently, the potential of communication trainings to reduce unnecessary caesarean sections needs to be investigated in the future.

Initially, the reasons for drop-out in this study might seem to be related to a (perceived) lack of safe care at the university hospitals. The pregnant women and their partners might have chosen a different hospital or birth center because of safety concerns; however, there are alternative explanations. The hospitals were located in areas with a number of alternative options. The study was conducted during the COVID-19 pandemic and the university hospitals had strict containment measures such as access restrictions. This might have caused families to choose different hospitals or birth centers which could have posed a risk for women with high-risk pregnancies. Due to capacity limits, the hospitals alshad to transfer women with low-risk pregnancies to remain functional for high-risk pregnancies. The high prevalence of high-risk pregnancies at the university hospitals could also explain why some women had to be treated because of a critical health status after birth.

Finally, it has to be considered that there was a substantial increase in nearly all study variables over time when aggregated over groups. In the control group, communication behavior, outcome expectancies/perceived birth outcomes and the HAPA variables increased. The effect of the training program showed in slightly higher increases in the intervention group. Hence, it must be discussed whether the slightly higher improvements in the intervention group actually pose an advantage over the passive control group. It is possible that scores obtained in the control group are sufficiently high to achieve a self-determined, positive birth experience; the high levels in the control could reflect an overall good standard of obstetric care. However, it is also possible that the “less than perfect” scores in the intervention group were still too low to achieve this aim. Nevertheless, the ITT analyses confirmed an increase in communication behavior, perceived birth outcomes and coping self-efficacy which are all important factors for a self-determined birth. Negative birth experiences have detrimental effects on bonding, maternal adjustment and long-term psychological outcomes (Simpson et al., 2018; Simpson & Catling, 2016). Consequently, it can be assumed that even slight increases in communication are important in obstetric care as negative experiences and birth-related post-traumatic symptoms are alarmingly common, leading to both worse maternal and fetal outcomes as well as the need for (expensive) psychological and medical interventions (Hollander et al., 2017). Antenatal prevention programs seem promising in avoiding at least some negative experiences and their consequences. They might be even more effective as part of existing childbirth classes, where more time and consideration can be given to pre-natal communication, thus providing a potential for even higher effects.

Limitations

When interpreting the results at hand, there are some limitations to consider. Firstly, because there is no reason to assume a selective dropout, we considered missing values as missing at random. Nevertheless, there were differences in outcome expectancies, coping self-efficacy and coping planning between those who dropped out and those who did not (according to the respective study group). In the intervention group, 63.1% of the pregnant women who provided baseline data also answered the questionnaire after birth, whereas 72.4% of the women in the control group did so. This contrast cannot be explained at the moment. We applied an ITT approach with multiple imputed datasets and compared the results with the initial (per protocol) analysis. Not all differences between groups could be found in both analyses. Hence, the effectiveness of the training regarding perceived patient safety, coping self-efficacy, and action planning remains questionable.

Furthermore, although the study design envisaged a randomization for the recruited mothers-to-be, it could not be fully realized for all participants. This is an important aspect to consider when interpreting the results, especially because the number of women who were not randomly assigned differed between groups. Indeed, 52 had to be assigned to the control group due to the imminent date of birth and 12 were allocated to the intervention group to fill the first two online training sessions. This imbalance means that a higher percentage of women in the control group were not randomized. Hence, the women in the control group are less likely to be representative of pregnant women at the hospitals who receive care-as-usual. Consequently, the role of the intervention might have been over- or underestimated. Although these assigned participants were recruited similarly to all other participants, it cannot be fully ruled out that this partial lack of randomization has caused a difference in study variables between the groups.

Another important point is that women in the control group did not receive any education or intervention which reduces the internal validity in comparison to an active control treatment. Alternative and unspecific mechanisms could explain the difference between groups, for example, by the fact that women in the intervention group spent more time with the topic of communication. Hence, they might have given more positive ratings after birth even if their communication behavior did not increase. The same could be true for perceived safety and quality of birth because the pregnant women might have felt that they received a higher quality of care because the hospitals actively took part in an according research project. Additionally, the randomization and the groups were transparent due to ethical concerns to ensure full informed consent, especially because the control group was a passive one. This might have caused treatment bias because there was no double-blind standard and women in the control group might have been disappointed to not receive the training.

In addition, the intervention was delivered in a group setting. Although participants were asked to actively engage with their own concerns and problems, this study did not assess nor tailor the intervention to specific individual needs. As the HAPA is a phase-specific model and different stages of change can be addressed in individuals, tailoring interventions to the participants' current stages would be an interesting way to implement communication trainings in the future. Furthermore, this study did not incorporate all HAPA variables that have been found to influence behavior change, such as action self-efficacy and risk perceptions to keep the questionnaires feasible and acceptable. It was decided to focus on the aspect of coping in self-efficacy and planning because giving birth is challenging and to help women preparing to communicate safely even under difficult circumstances. Nevertheless, future research could evaluate the role of action self-efficacy and risk perceptions in safe communication.

Furthermore, subjective measures and single-item scales were used to ensure that the questionnaires were feasible shortly before and after giving birth. Due to differential intervention effects and the role of the birth itself, it is likely that they had a low reliability and the internal consistency for the communication scale was low at T1. Finally, the study sample mainly consisted of highly educated native speakers, who gave birth at university hospitals. Therefore, the education status and the high level of care may be limiting the generalizability of results.

Recommendations for future research

This study is, to our knowledge, the first to develop a theory-based communication intervention for pregnant women based on a behavior change theory and to evaluate it in a systematic research design. In former research, interventions have strongly focused on medical professionals in teamwork training approaches (Cornthwaite et al., 2015). Our study focused on enabling women to voice their needs and concerns by understanding communication behavior as a health-related behavior that builds on social-cognitive determinants. Future research should explore whether these determinants and other behavioral factors derived from behavior change theories moderate or mediate improvements in communication while applying best practice research designs.

As indicated, the study sample at hand mostly consisted of highly educated women who were German speakers. However, it is well-known that patients from minority cultural backgrounds are at a higher risk for experiencing pAE and subsequent harm (Coffey et al., 2005). Furthermore, communication interventions can be helpful for patients with low literacy, but also cause unwanted side effects (Roter et al., 2015). Hence, future

research should evaluate whether behavior change theories are applicable to women from different backgrounds and whether behavioral factors and processes are similar to the ones we found in our study.

Performing the training in a digital workshop mode was feasible, especially against the background of the worldwide COVID-19 pandemic in which face-to-face training was hardly reasonable. This is in line with recent findings indicating that digital antenatal classes were a good solution (Wu et al., 2020). Nevertheless, communication remains an interpersonal process in which a face-to-face mode might be more effective. Then again, an in-person training might need more resources so that an online training program (without an instructor) might be more cost-effective. Therefore, future research should compare different modes with the same evidence-based interventions.

Regarding future evaluation, there are different potential outcomes to focus on. Although subjective perceptions of childbirth are crucial for the adaption to motherhood and for long-term well-being (Simpson et al., 2018), a key target in healthcare is the principle to “Do no harm,” that is, to avoid pAE. Hence, objective patient safety measures should be applied. Although questions remain for future research, it is promising that such a short, online communication training targeting pregnant women’s communication behavior and its social-cognitive determinants resulted in an advantage, albeit small, in the intervention group. As argued above, the training was feasible and even small improvements in communication are a small step to avoid risks for patient safety, create more self-determined births as well as facilitate adaption after giving birth. However, hospitals and care providers need to ensure that all pregnant women can be educated and trained in safe communication. Possibilities to do so are the inclusion of communication interventions in existing antenatal courses or information events. Health scientists can apply evidence and theory to facilitate and sustain behavior change.

CONCLUSION

To summarize, this study provides preliminary evidence for an online communication intervention for pregnant women based on a health behavior change theory, namely the HAPA. Positive effects were found in both the per protocol and ITT analyses for communication behavior, birth outcomes as well as coping self-efficacy, but could not be confirmed in ITT analyses for perceived patient safety risks, action planning and coping planning. Hence, the use of psychological and behavior change theories to target communication behavior in clinical practice should be further investigated. The implementation in routine care will require adjustments to different contexts, cultural backgrounds, and languages. Thus, future research should evaluate these adaptations and examine potential moderators and mediators of training success regarding communication behavior and objective patient safety data.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

ETHICS STATEMENT

The research project was previously registered ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03855735) Identifier: NCT03855735). Ethical approval for the data collection and online training was granted as part of the TeamBaby ethical approval from the University Hospital of Ulm Human Research Ethics

Committee (Number 114/19) and the University Hospital of Frankfurt Medical Research Ethics Committee (Number 19-292). All study participants provided written, informed consent to participate in the study.

DATA AVAILABILITY STATEMENT

All data, analysis code, and research materials are available upon reasonable request to the corresponding author.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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