EXPLICIT PROGNOSTIC DISCLOSURE TO ASIAN WOMEN WITH BREAST CANCER: A RANDOMIZED SCRIPTED VIDEO-VIGNETTE STUDY (J-SUPPORT1601)

Running title: Explicit prognostic disclosure to Asians

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Condensed abstract: In this randomized, video-vignette study involving 105 Japanese women with breast cancer, participants showed significantly lower uncertainty and higher satisfaction without increasing anxiety after viewing the video with more vs. less explicit disclosure. When asked about the prognosis by Asian cancer patients, clinicians may be encouraged to respect their wishes and explicitly discuss the prognosis if deemed appropriate.

ABSTRACT

Background

Non-disclosure of a poor prognosis to advanced cancer patients remains a typical practice in Asia. Although the importance of prognostic communication has increasingly been recognized worldwide, little is known about whether explicit prognostic disclosure positively affects Asian patients with advanced cancer. We aimed to examine the effects of explicit prognostic communication on patients with cancer recurrence.

Methods

In this randomized, video-vignette study, Japanese women with breast cancer who had undergone curative surgery viewed videos of prognostic communication between a patient with recurrent incurable breast cancer and her oncologist. The videos differed only in the presence/absence of explicit prognostic disclosure. The primary outcome was participants' uncertainty (0–10), and the secondary outcomes included anxiety (State-Trait Anxiety Inventory (STAI)-State (20–80)), satisfaction (Patient Satisfaction Questionnaire (0–10)), self-efficacy (0–10), and willingness to discuss advance care planning (ACP) (1–4).

Results

In total, 105 women participated (age=53.8±8.2). After viewing the video with more vs. less explicit disclosure, participants showed significantly lower uncertainty (5.3[SE, 0.2] vs. 5.7[0.2], respectively,

p=0.032) and higher satisfaction (5.6[0.2] vs. 5.2[0.2], respectively, p=0.010) without increasing anxiety (changes in STAI-State, 0.06[0.5] vs. 0.6[0.5], respectively, p=0.198). No significant differences were observed in self-efficacy (5.2[0.2] vs. 5.0[0.2], respectively, p=0.277) or willingness to discuss ACP (2.7[0.1] vs. 2.7[0.1], respectively, p=0.240).

Conclusions

Explicit prognostic disclosure prompted better outcomes than non-disclosure in Japanese women with breast cancer. When asked about the prognosis by Asian cancer patients, clinicians may be encouraged to respect their wishes and explicitly discuss the prognosis if deemed appropriate.

Key words: Prognostic disclosure, explicitness, uncertainty, video-vignette study, bad news

Total number: 29 pages; 3 tables; 1 figure; 1 appendix

BACKGROUND

Explicit prognostic disclosure to advanced cancer patients is considered important, as it can reduce uncertainty about the future, and enable them to engage in realistic decision-making and receive goal-concordant care [1, 2]. Literature from Western countries has demonstrated that the majority of advanced cancer patients prefer prognostic communication with their oncologists, and that approximately 70% of oncologists would disclose the prognosis at the time of diagnosing metastatic cancer [2-5]. Furthermore, advanced cancer patients who had been told the prognosis had a more realistic prognostic estimation and accurate illness understanding than those who had not been told, without worsening anxiety or adversely affecting the physician-patient relationship [2, 6]. Several guidelines from Western countries strongly recommend that physicians provide prognostic information that is tailored to the patient's needs and coping styles to facilitate advance care planning (ACP) [7-9].

Like Western countries, the importance of self-determination has increasingly been recognized in several Asian countries; nowadays, most Asian patients are told of the diagnosis of cancer, and ACP is promoted at a national level [10-12]. However, disclosure of a poor prognosis is not common in communication with advanced cancer patients of Asian origin, as non-disclosure of bad news and a family-centered decision-making style remain typical practices in Asian culture [12-15]. For example, previous surveys in East Asia showed that most physicians would not discuss EOL issues including a poor prognosis with advanced cancer patients [14, 15]. Other surveys also revealed that up to 40–50% of

Japanese and Japanese-American people either did not want to discuss the prognosis at all or preferred some level of negotiation with the physician [16-18]. Likewise, non-disclosure of a poor prognosis was shown to be favored among Chinese migrant cancer patients and their families in Australia [12]. Without prognostic information, however, advanced cancer patients may suffer marked uncertainty [1]. Uncertainty is the inability to determine the meaning of illness-related events, especially ambiguity and unpredictability of future medical conditions (e.g., treatment effects, rate of disease progression, and their impact on the prognosis) [19-21]. Furthermore, uncertainty has been shown to correlate with more marked symptoms, anxiety and psychological distress, and a negative attitude toward health care [22-24].

Thus, whether explicit prognostic disclosure has positive effects and recent guidelines from Western countries are applicable on communicating with advanced cancer patients with an Asian origin must be examined. The primary aim of this study was to examine the effect of explicit prognostic disclosure on uncertainty at the time of cancer recurrence in Japan. We also explored whether explicit prognostic disclosure improves patient satisfaction without worsening anxiety, and whether it improves patient self-efficacy and willingness to discuss ACP.

METHODS

This is the primary report of a randomized, crossover, scripted video-vignette study that aimed to examine the effects of explicit prognostic disclosure. Video-vignettes have been widely utilized to

elucidate optimal communication skills in clinical settings of end-of-life discussions on such topics as a poor prognosis, the cessation of life-prolonging treatment, and code status [1, 25-28]. For the entire study, we used an experimental 2 x 2 design to investigate verbal communication elements (i.e., explicitness) as well as non-verbal ones (i.e., eye contact). The primary analysis was determined *a prior* to investigate the effects of explicitness (more versus less) on uncertainty in Japan, and the effects of the non-verbal components will be reported separately as a secondary analysis. Although this study applied the similar design to that of the previous study in the Netherlands, ours is unique in that the effect of explicit prognostic disclosure was tested for the first time in the Eastern culture where such disclosure is not common. The study of van Vliet, et al. was conducted in the Netherlands and included no participants from an Asian background but almost completely participants with a Western European background [1]. Also, the patient and oncologist depicted in the vide were of Caucasian background [1]. The ethical and scientific validity of the study was verified by the institutional review board at the National Cancer Center in Japan.

Participants

Women with breast cancer who were seen in outpatient clinics in the Departments of Breast Surgery and Breast and Medical Oncology at National Cancer Center Hospital were recruited from August 2016 to March 2017. The inclusion criteria were women who: 1) were aged 20 or older; 2) had invasive breast cancer; 3) did not have breast cancer recurrence, and were receiving adjuvant targeted

therapy and/or hormone therapy, or had completed adjuvant chemotherapy, targeted therapy, and/or hormone therapy; 4) had undergone breast cancer surgery more than one year before enrollment; and 5) had been informed of their cancer diagnosis. Women were excluded if they: 1) had severe cognitive impairment; 2) could not read or write Japanese; 3) had difficulty in using a touch panel; 4) were actively receiving chemotherapy for breast cancer or other cancers; 5) participated in another intervention study; or 6) their participation was considered inappropriate by their oncologist. There was no outer limit in time from diagnosis.

Study design

Video development

Based on the previous study [1] and following the recommended steps for creating experimental video-vignettes [29, 30], four scripted video-vignettes were developed in which an oncologist discussed the prognosis with a female patient who was just diagnosed with breast cancer recurrence and metastatic disease. These video-vignettes were identical in content, length (5 minutes 10 seconds ± less than 10 seconds), and communication, but the "explicitness of the prognosis" varied systematically between the vignettes (more vs. less; Appendix). The scripts and manipulations were developed based on a previous study [1]. An introductory video (2 minutes) was developed in which the video-patient introduced herself and expressed her feelings about the upcoming consultation, which aimed to increase participants' emotional involvement.

To ensure the scripts' internal/external validity, both lay people (breast cancer survivors, healthy women) and experts (oncologists, palliative care physicians, and communication experts) were involved in creating the written and role-playing scripts, and confirmed their life-like nature, contents, and the manipulation success. Clinicians role-played using the scripts to convey a sense of realism, and the videos were filmed and edited by a professional company.

Procedure and data collection

Each participant was separately invited to a dedicated, quiet study room. After informed consent was obtained, their background characteristics were assessed. The order of the presentation of the four videos was randomly allocated in advance. The detailed procedure of random allocation was not disclosed to the researchers. All participants watched all four videos in a random order (24 patterns of order (4x3x2x1)). They were then asked to identify with the video-patient. First, they watched the introduction video and the first part of the consultation regarding her cancer recurrence. Then, they watched the four different videos. Anxiety was assessed before each video and all outcome measures were assessed after each video. A distraction task was provided between the videos (looking at an aquarium while listening to background classical music). The validity of this approach has been previously documented [31, 32]. All videos were displayed and questionnaires were completed on iPads.

Primary outcome measure

Uncertainty (0 – 10, self-rated numerical rating scale (NRS), ranging from 0=very certain to 10=very uncertain) was the primary outcome measure [1]. We applied an NRS rather than a visual analog scale (0 – 100) which has previously been used [1], as the former was considered more familiar and easily understandable to Japanese patients. We asked the participants to do the following: "please indicate the extent to which the manner of the doctor's communication has made you uncertain about your future". This request was developed based on a previous study [1], and it underwent a formal forward-back translation process including the principal investigator of the previous study as well as cognitive testing with breast cancer survivors.

Secondary outcome measures

Secondary outcome measures were anxiety (State-Trait Anxiety Inventory (STAI)-State), satisfaction (Patient Satisfaction Questionnaire (PSQ)), self-efficacy, and willingness to discuss ACP. The STAI State consists of 20 items with responses on a 4-point Likert scale, with a higher score indicating more marked anxiety [33]. The validity and reliability of the Japanese version have been previously confirmed [34]. We used the difference between STAI-State scores before and after each video. The PSQ measures participants' level of satisfaction about communication with a physician measured on 5 items (reliability, 0.90) [1, 35]. The response was rated on an NRS (0 – 10) with a higher score indicating a higher level of

satisfaction, and the mean scores of the 5 items were calculated. We performed a formal forward-backward translation. Self-efficacy was rated on an NRS (0 – 10), ranging from a very weak to very strong belief in the ability to deal with the future [1]. Lastly, we rated participants' willingness to discuss ACP including life-sustaining treatment and the preferred place of death such as hospice/inpatient palliative care unit with their oncologist on a 4-point Likert-type scale (1=very unwilling to 4=very willing) [3, 15, 36].

The success of the manipulation—how explicit the prognostic information was perceived as being—was measured using a 10-point scale ("not at all" to "very") [1].

Background measures

We measured the following characteristics: demographic variables, physical/psychological symptoms (physical and emotional symptom scores of the Edmonton Symptom Assessment System-revised, Japanese version (ESAS-r-J) [37, 38]), preferences for prognostic disclosure ('not to discuss at all', 'physician to inform me only if I ask', 'physician to check with me first whether I want to know', or 'physician to initiate a discussion and inform me in detail') [16, 18], coping styles (Coping Inventory for Stressful Situations (CISS) [39, 40]), and whether participants had experiences with loved ones receiving a life-limiting cancer diagnosis ("similar experiences" [1]) , as they could influence the level of uncertainty [1, 19, 22-24, 41, 42]. The CISS is a 48-item instrument that distinguishes three basic coping strategies with 16 items per scale: task-oriented, emotion-oriented, and avoidance. The score of each item ranges from

1=not at all to 5=very much, and scores for all items per scale are summed to form scale scores, with a higher score signifying a greater use of that particular coping strategy. With regards to ESAS-r-J, scores of physical (pain, tiredness, drowsiness, nausea, lack of appetite, and shortness of breath) and emotional (depression and anxiety) items were summed to form ESAS-physical (0 – 60) and ESAS-emotional (0 – 20) scores, respectively, with a higher score indicating a greater symptom intensity [38].

Statistical analyses

We applied the general linear model for the evaluation of a 2×2 intervention of the presence/absence of explicit prognostic disclosure and that of eye contact. The score of uncertainty was used as the response variable, and more/less explicitness of prognostic disclosure, that of eye contact, those interactions, and time were included as explanatory variables in the primary analysis. Robust variance was used with consideration of intra-subject correlations of the scores. We estimated the average value of each score with and without both interventions (the four videos) and tested the differences in the mean values for each intervention. The main concern was the main effect of explicit prognostic disclosure. Multivariate regression analyses were used to explore the association between the outcome measures and background factors. We combined the data on the effects of eye contact (more vs. less) within each group, as no interaction was observed between the effects of explicitness and eye contact.

Sample size

With reference to a previous study by van Vliet et al. [1], we estimated that the difference in the mean uncertainty score (primary outcome measure) between the more/less explicitness of prognostic disclosure was 0.8 points, the standard deviation of score 1, and the magnitude of the intra-patient correlation was 0.2. With a significance level of the test in the primary analysis of 5% (two-sided) and a power of 80%, 22 patients would be needed; thus, we set the sample size at 24 in consideration of patient dropout, etc. To control for the order effect of a 2×2 intervention, 24×2×2=96 subjects would be needed, and 105 subjects were targeted for conclusion.

We conducted a pilot test with 8 eligible women, examined the mean scores of the primary outcome (more explicit disclosure: mean of uncertainty, 4.8; less explicit disclosure: mean, 5.4), and confirmed the appropriateness of this sample size calculation before initiating the official patient enrollment. The subjects included in the pilot test were not included in the main cohort.

RESULTS

Participants' characteristics

Of the 219 women with breast cancer who were approached, 105 (48%) consented and participated, 1 withdrew her consent, 3 did not show up to give consent on a scheduled day, and 110 declined. The reasons for the decline included the lack of time (n=92), psychological burden (n=9), no

interest (n=1), and other (n=8) (Figure 1). The participants' mean age was 53.8. Baseline characteristics of the participants are summarized in Table 1.

Manipulation check

The manipulations succeeded. In the more explicit videos, the prognosis was evaluated as being more explicit than in the less explicit videos (more explicit disclosure: mean, 5.7; standard error (SE), 0.2; less explicit disclosure: mean, 4.8; SE, 0.2; $p<0.001$).

Effects of the videos

After viewing the videos with more vs. less explicit disclosure, participants exhibited significantly lower uncertainty (5.3[SE, 0.2] vs. 5.7[0.2], respectively, p=0.032) (bivariate analyses, Table 2). They also exhibited higher satisfaction after viewing the video with more explicit disclosure (5.6[0.2] vs. 5.2[0.2], respectively, p=0.010). No significant differences were observed in changes in STAI-State scores (0.06[0.5] vs. 0.6[0.5], respectively, p=0.198), self-efficacy (5.2[0.2] vs. 5.0[0.2], respectively, p=0.277) or willingness to discuss ACP (2.7[0.1] vs. 2.7[0.1], respectively, p=0.240) after viewing the videos with more vs. less explicit disclosure.

Factors contributing to the uncertainty

Multivariate regression analyses (Table 3) revealed that a higher ESAS-Emotional score was a significant and independent determinant of a lower uncertainty (β=-0.12, p=0.013) and stronger willingness to discuss ACP (β=0.05, p=0.009). In addition, a higher CISS Emotion-oriented score was a significant and independent determinant of a higher uncertainty (β=0.05, p<0.001) and lower satisfaction (β=-0.04, p=0.008), self-efficacy (β=-0.04, p=0.004), and willingness to discuss ACP (β=-0.03, p<0.001). An order effect was also noted with respect to uncertainty: the first (β=1.42, p<0.0001) and second (β=0.70, p=0.049) videos as compared with the fourth one were independent determinants of a higher uncertainty after viewing the videos.

DISCUSSION

To the best of our knowledge, this is the first empirical study to demonstrate the effects of explicit prognostic disclosure on cancer patients with an Asian origin. The first and most important finding is that explicit prognostic disclosure significantly reduced uncertainty and increased satisfaction without causing increased anxiety in Japanese women with breast cancer. These findings are consistent with previous studies in Western countries [1, 2], and add a new insight into the impact of explicit prognostic disclosure on patients from Asian countries. Traditionally, non-disclosure of bad news including a poor prognosis to a patient has been common practice, and the role of the family in liaising between clinicians and the patient has been emphasized in Asian culture [12-14]. Even within a single ethnic population, such as the Japanese, people

living in Japan are less likely to value knowing what to expect about one's condition in the future and more likely to value leaving the decision to a medical expert than Japanese-Americans [18]. With regard to prognostic disclosure in an incurable cancer setting, those living in Japan are more likely to prefer no disclosure at all than Japanese-Americans [18]. However, generalizations, such as an Asian culture, could lead to stereotyping. Especially in this globalization era, the traditional cultural norm should not prevent clinicians from exploring individual preferences and information needs. Our findings suggest that while the amount of prognostic disclosure should still be tailored to patients' preferences, explicit disclosure might have an overall positive impact on Japanese patients when they ask their physicians about their prognosis, and may reassure physicians that the disclosure itself does not necessarily cause anxiety.

The second important finding is that several factors were shown to contribute to patient outcomes. Order effects have repeatedly been demonstrated in previous video-vignette studies in which earlier videos led to more negative outcomes [25, 28]. Factors that were significantly correlated with more than one outcome included ESAS-Emotional score and emotion-oriented coping. While the prior literature indicated that marked physical symptoms were associated with lower uncertainty [41], little is known about whether emotional distress could lead to lower uncertainty. As the overall intensities of physical and emotional symptoms were low in our patients, these findings may indicate that modest levels of anxiety and depression in patients should not preclude prognostic communication if deemed necessary. Furthermore, emotion-oriented coping consistently led to negative outcomes after prognostic disclosure.

To the best of our knowledge, no study has explored such an association. However, emotion-oriented coping has been reported as a maladaptive coping style [43-46], and a prior study of gynecological patients undergoing surgery suggested that emotion-oriented coping led to a significantly more severe perioperative emotional status [47]. These findings suggest that clinicians should provide extra support when communicating prognoses to patients who tend to exhibit emotional responses to stressful situations (e.g., get angry, become tense, blame themselves for being too emotional). The multivariate analyses (Table 3) were explanatory, and their purpose was to explore potential factors other than explicitness which could influence uncertainty. Our main concern of this study was the main effect of explicit prognostic disclosure on uncertainty. To confirm its effect, we had utilized a randomized controlled design, and estimated the sample size based on the binary analysis, which was specified as primary analysis in the protocol. Thus, the result of the binary analysis shown in Table 2 is the most important and valid. The multivariate analyses also indicated that explicitness tended to be associated with lower uncertainty, which is in line with the main analysis.

Of note, though explicit prognostic disclosure tended to improve self-efficacy, the difference did not reach significance, unlike in a previous study [1]. Furthermore, explicit disclosure did not improve the willingness to discuss ACP. Cultural differences may have contributed to these negative findings. Unlike Western culture that values individualism, independence, and autonomy as individual, Asian people generally value collectivism, interdependency, and autonomy as a family, resulting in a more family-

centered decision-making process [48-51]. Thus, patients in Asia may find it challenging to develop self-efficacy in their ability to deal with the future and willingness to discuss ACP without having discussions with their loved ones. In addition, improvement of self-efficacy and willingness for discussion is a part of the complex process of ACP [52]. Future studies are needed to elucidate the longitudinal effects of prognostic disclosure combined with multifaceted ACP interventions involving not only patients but also their loved ones with an Asian origin.

Despite the strengths of a randomized design, our study has several limitations. First, we conducted an experimental study with women with breast cancer following curative surgery. A previous systematic review showed the validity of a randomized scripted video-vignette study [31]. However, our subjects were patients that were well at the time of study participation, although potentially at risk of recurrence in the future. Thus, the emotional reactions of patients with metastatic disease might be more intense in actual situations. Second, we recruited relatively young participants at a single cancer center in the Tokyo metropolitan area. They may have been more open to explicit discussion, and thus one should exercise caution when generalizing our findings to older women or those living in rural areas in Japan, as well as those in other Asian countries or to Asian patients in Western countries with various levels of acculturation [18]. Third, the video-vignette patient asked for explicit prognostic information. Whether the same results would be generated if this was not the case remains to be determined. Fourth, we did not pre-determine the threshold for clinically meaningful difference with regard to the primary endpoint. To the

best of our knowledge, there is no current consensus or guideline of a clinically meaningful difference. Thus, the statistically significant between-group difference in uncertainty might not fully represent clinically important difference. Lastly, experimental designs inherently reduce the complexity of clinical interactions, which underlines the importance of future prospective studies in a real-world setting.

In conclusion, explicit prognostic disclosure led to better outcomes than non-disclosure in Japanese women with breast cancer. When cancer patients with an Asian origin ask about the prognosis, clinicians may be encouraged to respect their wishes and explicitly discuss the prognosis if deemed appropriate.

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Table 1. Baseline characteristics of participants

Characteristics	No.	%	Mean	SD
Age			53.8	8.2
Sex, female	105	100		
Marital status				
Married	68	65		
Single (divorced/widowed)	37	35		
Stage				
I	50	48		
II	42	40		
III	13	12		
Subtype				
ER or PgR-positive, HER2-negative	65	62		
ER or PgR-positive, HER2-positive	28	27		
ER and PgR-negative, HER2-negative	4	4		
ER and PgR-negative, HER2-positive	8	8		
Treatment history				
Surgery (years ago)			3.3	2.7
(Range, years)			(1.0 – 15.6)	
Radiation therapy, Yes (%)	68	65		
Cancer drug therapy				
Hormone therapy	92	88		
Chemotherapy	63	60		
Targeted therapy	36	34		
ECOG PS				
0	81	77		
1	23	22		
2	1	1		
Highest education				
Low/medium (<high school/vocational education)	71	68		
High (university/graduate school)	34	32		
Annual income (dollars)				
<20,000 dollars	9	9		

20,000 – 40,000	23	22		
40,000 – 60,000	25	24		
60,000 – 80,000	14	12		
>80,000	35	33		
Occupation				
Paid job	70	67		
No paid job (including unemployed/housewife/student)	35	33		
Family situation				
Lives with children≤20 years of age, Yes (%)	24	23		
Lives with parents requiring care, Yes (%)	20	19		
Family/close friends who died of advanced cancer, Yes (%)	56	53		
Symptoms (ESAS-r-J)				
Physical score			5.3	5.6
Emotional score			2.5	3.2
Preferences for prognostic disclosure				
Not to discuss at all	1	1		
Physician to inform me only if I ask	18	17		
Physician to check with me first whether I want to know	28	27		
Physician to initiate discussion and inform me in detail	48	55		
Coping styles (CISS)				
Task-oriented			58.5	10.3
Emotion-oriented			39.3	10.5
Avoidance			50.1	10.8

The ESAS physical score (0-60) represents the sum of ESAS pain/tiredness/drowsiness/nausea/lack of appetite/shortness of breath. The ESAS emotional score (0-20) represents the sum of ESAS depression/anxiety.

Abbreviations: SD, standard deviation; ER, estrogen receptor; PgR, progesterone receptor; HER2, human epidermal growth factor receptor-related 2; ECOG PS, Eastern Cooperative Oncology Group Performance Status; ESAS-r-J, Edmonton Symptom Assessment System revised, Japanese version; CISS, Coping Inventory for Stressful Situations.

Table 2. Main effects of explicit prognostic disclosure on outcomes

	Explicitness (+)		Explicitness (-)				
Effect	Mean	SE	Mean	SE	Difference	95% CI	*p*
Uncertainty [a]	5.3	0.2	5.7	0.2	0.4	0.04, 0.8	0.032
Satisfaction [a]	5.6	0.2	5.2	0.2	-0.4	-0.7, -0.1	0.010
Anxiety: STAI-State [b]	0.06	0.5	0.6	0.5	0.6	-0.3, 1.4	0.198
Self-efficacy [a]	5.2	0.2	5.0	0.2	-0.2	-0.6, 0.2	0.277
Willingness to discuss ACP [c]	2.7	0.1	2.7	0.1	-0.1	-0.2, 0.1	0.240

[a]: Scores range from 0 – 10 (low-high)

[b]: Differences in scores (20 – 80, low-high) before and after viewing the video

[c]: Score ranges from 1 – 4 (low-high)

Abbreviations: SE, standard error; CI, confidence interval; STAI, State-Trait Anxiety Inventory; ACP, advance care planning.

Table 3. Factors contributing to the patient outcomes

	Uncertainty			Anxiety			Satisfaction			Self-efficacy			Willingness to discuss ACP		
	β	*SE*	p	β	*SE*	p	β	*SE*	p	β	*SE*	p	β	*SE*	p
Order of video															
First	**1.42**	**0.35**	**< 0.001**	-1.19	0.70	0.088	-0.18	0.32	0.579	-0.15	0.37	0.694	0.28	0.13	0.032
Second	**0.70**	**0.35**	**0.049**	-1.13	0.73	0.121	-0.09	0.33	0.783	-0.01	0.39	0.979	0.12	0.13	0.335
Third	0.12	0.41	0.767	0.42	0.68	0.540	0.04	0.36	0.923	0.19	0.42	0.654	0.06	0.14	0.649
Fourth (Ref)	0			0			0			0			0		
Explicitness, no vs. yes (Ref)	0.44	0.25	0.074	0.51	0.69	0.461	-0.41	0.23	0.078	-0.21	0.27	0.432	-0.09	0.10	0.371
Age	-0.00	0.02	0.991	-0.00	0.05	0.962	-0.00	0.02	0.936	0.00	0.02	0.914	-0.00	0.01	0.918
Marital status, married vs. single (Ref)	0.39	0.29	0.178	-1.50	0.83	0.072	-0.02	0.28	0.950	0.29	0.34	0.393	0.07	0.10	0.460
Highest education, high vs. low/medium (Ref)	0.46	0.29	0.116	-0.48	0.85	0.578	-0.06	0.27	0.839	-0.33	0.32	0.310	0.04	0.11	0.696
Subtype															
ER and PgR-negative, HER2-positive	0.93	0.53	0.084	-0.91	1.29	0.483	0.61	0.58	0.291	0.90	0.66	0.178	0.05	0.24	0.839
ER and PgR-negative, HER2-negative	0.45	0.85	0.600	-0.17	2.93	0.955	-0.79	0.54	0.146	-0.57	0.64	0.370	**-0.91**	**0.34**	**0.008**
ER or PgR-positive, HER2-positive	0.34	0.37	0.369	1.51	1.12	0.178	0.08	0.32	0.800	-0.14	0.41	0.739	0.07	0.13	0.608
ER or PgR-positive, HER2-negative (Ref)	0			0			0			0			0		
Treatment history															
Years since surgery	0.05	0.05	0.277	0.02	0.13	0.863	-0.04	0.04	0.365	0.06	0.05	0.208	0.01	0.02	0.554
Radiotherapy, yes vs. no (Ref)	0.47	0.31	0.131	-0.37	0.79	0.643	-0.15	0.28	0.598	-0.37	0.34	0.280	-0.20	0.11	0.077

Neoadjuvant and/or adjuvant chemotherapy, yes vs. no (Ref)	-0.08	0.35	0.816	-0.47	0.84	0.574	-0.33	0.35	0.344	-0.29	0.41	0.481	-0.14	0.14	0.303
ECOG PS 1 – 2 vs. 0 (Ref)	-0.32	0.34	0.351	-0.09	0.87	0.918	0.20	0.28	0.483	-0.06	0.35	0.871	0.15	0.14	0.267
Stage, II/III vs. I (Ref)	-0.39	0.33	0.236	-1.42	0.91	0.118	-0.50	0.30	0.101	-0.70	0.37	0.061	0.08	0.13	0.552
ESAS-Physical	0.04	0.03	0.177	-0.01	0.08	0.926	-0.00	0.03	0.935	-0.01	0.03	0.716	**-0.02**	**0.01**	**0.044**
ESAS-Emotional	**-0.12**	**0.05**	**0.013**	0.09	0.13	0.487	0.06	0.04	0.172	0.03	0.05	0.582	**0.05**	**0.02**	**0.009**
CISS Task-oriented	-0.01	0.02	0.450	0.01	0.04	0.751	-0.01	0.02	0.510	-0.01	0.02	0.647	**-0.01**	**0.01**	**0.013**
CISS Emotion-oriented	**0.05**	**0.01**	**<0.001**	0.09	0.05	0.067	**-0.04**	**0.01**	**0.008**	**-0.04**	**0.02**	**0.004**	**-0.03**	**0.01**	**<0.001**
CISS Avoidance	-0.03	0.01	0.062	-0.07	0.04	0.068	0.02	0.01	0.215	0.02	0.02	0.142	0.01	0.01	0.123
Family or close friends who died of advanced cancer, yes vs. no (Ref)	0.34	0.28	0.230	-0.10	0.80	0.897	0.11	0.25	0.655	0.01	0.30	0.981	**0.26**	**0.11**	**0.017**
Preferences for prognostic disclosure, disclosure with or without negotiation vs. no disclosure (Ref)	-0.01	0.29	0.981	-0.34	0.80	0.670	-0.25	0.25	0.329	-0.26	0.30	0.378	**0.36**	**0.11**	**0.002**

High education indicates “university and graduate school”, and low/medium “less than high school and vocational education”. The ESAS physical score (0-60) represents the sum of ESAS pain/tiredness/drowsiness/nausea/lack of appetite/shortness of breath. The ESAS emotional score (0-20) represents the sum of ESAS depression/anxiety.

Significant values ($p<0.05$) are in **bold**.

Abbreviations: ACP, advance care planning; SE, standard error; Ref, reference; ER, estrogen receptor; PgR, progesterone receptor; HER2, human epidermal growth factor receptor-related 2; ECOG PS, Eastern Cooperative Oncology Group Performance Status; ESAS, Edmonton Symptom Assessment System; CISS, Coping Inventory for Stressful Situations.

Figure legend

Figure 1. CONSORT diagram

Abbreviation: EC, eye contact

Appendix 1. Final scripts including manipulations

Abbreviation	Camera perspective
CAM 1	Overview shot of patient/husband and oncologist
CAM 3	Shot oncologist
CAM 2	Shot patient/husband
T (total)	Total shot
M (medium)	Middle close up
C (close up)	Face close up
P	Patient
H	Husband
O	Oncologist
EC	Eye-contact

Introduction sequence

Verbal	Non-verbal
P: My name is Kazue Saito, I'm 45 years old. I live with my husband and two children; a 17-year-old girl and a 15-year-old boy. Two years ago I was diagnosed with breast cancer. I've had breast-conserving surgery to remove the tumor. To be on the safe side, I first received radiation therapy and afterwards chemotherapy to kill cells that may still be there but which cannot be seen. After a while, my life seemed to get back on track again. However, one month ago I felt a lump in the same breast. Of course, I was in shock and immediately called the hospital. I got an appointment with the surgeon right away. He did a physical exam and felt my lymph nodes. He didn't have a good feeling about it all, so last week I had a bone scan and CT	P + H are sitting in a waiting room. P talks. She looks anxious and nervous. From time to time, she stares and looks restlessly around her. She fiddles with her hands/fingers. Voice falters somewhat.

of my liver and lungs to see if the cancer has come back. I can't believe it. But I have an appointment with the doctor right now to get the test results. I haven't slept at all, I'm so uptight and I'm afraid the cancer is back.	

Diagnosis sequence

Verbal	Non-verbal
O: Hello Mr. and Mrs. Saito, my name is Dr. Suzuki. Please have a seat.	CAM1/T O opens the door and bows. P+H are sitting down, next to each other, facing O, who has also taken a seat.
O: So, you went to see the surgeon, Dr. Tanaka, after you felt a lump in your breast. Doctor Tanaka did an exam and suspected that the cancer might have recurred. Therefore, a puncture of a lymph node near the collarbone was done and both a bone scan and CT of your liver and lungs were conducted.	CAM3/M O talks calmly and looks at P + H.
P: Yes, that's correct. That all happened last week.	CAM2/M P makes eye-contact and looks away.
O: Yes, it all happened last week. I have the test results of the examinations. Unfortunately, I do not have good news for you. We have found metastases in the lymph node near the collarbone and the liver and bones.	CAM3/M O nods. Puts the patient charts in front of him. CAM2/C O talks slowly, showing imaging on the electronic medical record. P looks straight ahead. 1 second of silence.
P: Oh no.	P stares blankly ahead.
H: (H doesn't say anything as if to express the unbelievable nature of the news)	P looks down, and looks to H for a short duration.
P: Well…this does mean that you can't remove it, right?	Question is posed in a soft voice, but with eye-contact, though P looks downward.
O: With these kind of metastases, it is no longer possible to remove the cancer completely and cure you.	CAM3/M O is leaning forwards slightly.

However, I do not want to portray things better than they are.	O looks at P and H in a serious and calm manner.
P: I still feel fine… I can't die. Especially for the kids!	CAM2/C P braces herself somewhat and leans forward.
O: Yes, that makes it more difficult to grasp doesn't it?	P looks forward.
P: Yes, but how bad is it?	She does pose the question firmly and with eye-contact.
O: What do you mean exactly?	CAM3/M O hesitates for a moment. [EC+] O leans forwards. [EC-] O moves his head slightly toward P

Prognosis sequence – less explicitness

Verbal	Non-verbal
P: How long have I got?	CAM2/M
O: Your life-expectancy?	CAM3/C O sounds a bit uncomfortable/asks for confirmation.
P: Yes, as a rough idea. I would like to know for my kids. Do you know that in general terms?	CAM2/M P looks at O in a firm yet slightly anxious way.
O: That's very difficult to predict, because it can differ from person to person and depend on future treatment and your stamina. So no one knows your life-expectancy. You do have a very serious disease, which will limit your life expectancy. That is the only thing we can say for sure. There are women who live for quite a long time with the type of cancer you have, and there are women who live for a shorter time. The comments you often see on television or read in magazines, about 'you only have so long to live', aren't realistic, because we do not know that in any individual case… So, no, I don't know how it will be for you.	CAM3/C O nods his head to show his understanding, and starts to talk in a serious way.
P: Yes, I understand that. That's something you can't predict.	
O: No.	O nods his head. Leans backwards.

Prognosis sequence – more explicitness

Verbal	Non-verbal
P: How long have I got?	CAM2/M
O: Your life-expectancy?	CAM3/C O sounds a bit uncomfortable/asks for confirmation.
P: Yes, as a rough idea. I would like to know for my kids. Do you know that in general terms?	CAM2/M P looks at O in a firm yet slightly anxious way.
O: That's very difficult. But I can give you some concrete numbers and averages. Would you like me to discuss these with you?	CAM3/C O nods his head to show his understanding, and starts to talk in a serious way.
P: Yes.	
O: When we look at what is known from studies of patients with your type of cancer cells and metastases, 50% of the patients are still alive after 2 years. So half the people will live longer than 2 years, while the other half will die within 2 years. Some people might live much longer, maybe as much as 4 years, but others might only live for half a year. *P: Yes…, I understand that. So you can't predict which group I belong to?*	
O: No.	O nods his head. Leans backwards.

Treatment sequence

Verbal	Non-verbal
P: And what now?	CAM2/M
O: Where do we go from here? You have already had radiation and chemo after surgery. Our goal from now is to live for as long as possible with your cancer.	CAM3/C O looks a bit more confident. Leans slightly forward.

P: But what can you do?	CAM1/T
O: Because the cancer has spread and your cancer is not hormone-sensitive, we will treat you with chemotherapy rather than an operation or hormone therapy. If you want that, in principle, we will do three courses, every 3 weeks. Then we'll look at how you feel and how burdensome the treatment is, and how it goes physically, is it working, which we can see with a scan.	CAM3/M O leans backwards. O tries to talk calmly. CAM2/C P looks devastated, anxious.
	CAM1/T
P: So, chemo?	CAM3/C
O: Yes. That is something we do not need to decide immediately though. With chemo we might be able to suppress the growth of the tumor. But chemo does cause side-effects.	O continues to look at P attentively.
P: Yes… We (looks at H) have to discuss this; together with the family. However, I don't think we have a choice. I have to receive treatment for the children. That means everything to me.	CAM2/C P has her hand in front of her chest. P + H make eye-contact. P has a lump in her throat.
O: I understand. Therefore, I think that it would be a good idea to discuss in detail all the possibilities during our next appointment, if that's okay with you. Let's think about what we can do together. (Conversation fades away.)	CAM3/C O looks at P + H. He tries to temper the emotions by continuing the conversation in a matter of fact manner.