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Methodological reflections on body–mind intervention studies with cancer patients

Adriaan Visser [a,1,*], Alexandra Schoolmeesters [a], Machteld van den Berg [b], Nicolle Schell [c,2], Rianne de Gelder [d,3], Bart van den Borne [e]

[a] Rotterdam University, Institute of Health Care, Expertise Center Transitions of Care, Rotterdam, The Netherlands
[b] Helen Dowling Institute: Center for Psycho-oncology, Utrecht, The Netherlands
[c] Ministry of Health, The Hague, The Netherlands
[d] Erasmus MC, Rotterdam, The Netherlands
[e] Department of Health Education, Maastricht University, The Netherlands

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ABSTRACT

Objective: Methodological reflection on the content, results and limitations of three body–mind intervention studies with cancer patients (CPs) in order to improve the quality of studies on body–mind interventions and to raise the potential value for CPs.
Methods: A secondary analysis of a study on haptotherapy and two studies applying relaxing face massage, using a variety of well-being effect measures. Six methodological themes are discussed: (1) drop-out; (2) characteristics of participating patients, (3) participation of patients in other complementary interventions; (4) satisfaction of participants; (5) effects of the three interventions, and (6) role of response shift.
Results: The three interventions showed limited effects after controlling for relevant confounding factors. They are mainly the small sample sizes, the low intensity of the intervention, the possible inadequate measure moments and the use of other CAM that may be responsible for the absence of effects.
Conclusions: Body–mind interventions require more methodological reflections to develop attractive and effective interventions for CPs. Attention needs to be paid to measuring short term effects, practically fitting research designs, and response shift.
Practice implications: Interventions should be intensive, repeated and not too short. The implementation of interventions requires attention to several organizational factors in the health care.

1. Introduction

Cancer patients (CPs) are confronted with several emotional, social, and spiritual problems [1–3]. To raise their quality of life, CPs are often turning to the use of complementary and alternative medicine (CAM). Worldwide, 29–70% of the general population [4–14], and 42–50% of CPs and palliative care patients use yearly at least one form of CAM [15–26]. Massage and relaxation techniques are the forms of healthcare most commonly used [4–6,9–12,15,16,19,20,27].

By means of massage and touches, patients are learned to connect with their feelings, how to deal with their illness, with themselves, and with the world around them, leading to reduction in symptoms and improvement in quality of life [28–31]. This approach is a part of the mind–body medicine, defined as focusing on the interaction among the brain, mind, body, and behavior, and the powerful ways in which emotional, mental, social, spiritual, and behavioral factors can directly affect health [32]. We will use the term body–mind approaches, because the studied interventions are mainly focusing on bodily interventions.

In this article we reflect on six methodological themes, giving insight in the effects of three body–mind interventions studies for CPs. First we present in Box 1 the conclusions from several studies and reviews about the effects of massage, guided imagery, and relaxation training on the well-being of CPs. The conclusion is that a number of these studies show significantly positive effects on the well-being of CPs. However, in the reviews and in the studies, several methodological issues and limitations are discussed, which under-

* Corresponding author at: Abraham Kuyperlaan 91A, 3038 PG Rotterdam, The Netherlands. Tel.: +31 10 4677857.
E-mail address: adriaan.visser@planet.nl (A. Visser).
[1] During the studies at the Helen Dowling Institute: Center for Psycho-oncology, Utrecht, The Netherlands.
[2] During the study Erasmus MC, Rotterdam, the Netherlands.
[3] During the study Leiden University Medical Center, Leiden, the Netherlands.

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Box 1. Effects of body–mind interventions on the well-being of patients with cancer.

Several efforts have been made to study the effects of CAM on the well-being of patients with cancer as shown in reviews [25,33–40]. Studies indicate that various interventions such as massage, guided imagery and relaxation training, have beneficial effects on the well-being of hospitalized as well as ambulatory patients with cancer [28–30,41–51]. In massages decreases in anxiety [37,38,41,42,50,52–55], pain [22,26,34,35,38,39,43,44,46,47,55–57], depression [41,42,45,50], anger [42,58], mood disturbance [28,29,35,37,53,56–60], nausea [26,49,61], dyspnoea [26], and improvements in quality of life [44], fatigue [60], sleeping problems [62,63], and in gloomy/negative feelings [37,63], and immune and neuro-endocrine functioning [51,64] have been observed. Massages often are combined with use of aroma's and essential oils, which may raise the effects of massages, although it masks the pure effects of massages [e.g. 30,37,38,61,63,65–67], a reason to exclude these studies in this review about massages. We will also exclude studies on therapeutic touch (TT), which is not directly at touch, but using energy exchange [68].
Studies specific about the effects of relaxation therapies are presented in reviews [33,34,37,39,61] and several studies. These studies show a decrease in emotional suppression and improvements in quality of life of in- and out-patients [30,45,69–72], symptoms [71,73,74], fatigue [40,66], improvement in distress, mood, depression and anxiety [46,50,66,69,71,74,75–81], gloomy/negative feelings [48,50,66,69,70,73,74,79,82,83], sleeping [75], pain [40,47,48,73,80,83–87], and nausea and vomiting [49,72,74,76,80,88,89].

mine firm conclusions about the benefits of the interventions for CPs. Some studies show negative effects [47,69,76,96,100,101,33]. Only few studies are measuring the body perception by the patients [2,3].

1.1. Methodological reflections

A lot of methodological factors may influence the results of body–mind interventions for CPs [90]. It is out-of discussion that these studies would require a firm design, by preference a randomized controlled study [33,37,91–93]. In practice it is not always easy to realize due to e.g. failing or impossible blinding, randomization problems, finding an adequate control group, and small samples [33,90,94,95]. Further, we analyzed the following six methodological themes, as presented in Box 2.

1.2. Research questions

We did three experimental studies on body–mind interventions for CPs: one study about haptotherapy [105,106], and two studies about relaxing face massage [98,99]. In this article we discuss the following six methodological themes: (1) the extent of the drop-out; (2) the characteristics of the participating patients, (3) the control on the participation in other complementary interventions; (4) the satisfaction of the participant; (5) the differential effects of the three interventions, and (6) the role of response shift.

2. Methods of the three body–mind intervention studies

2.1. Haptotherapy at a day clinic for chemotherapeutical treated CPs

The purpose of this study was to evaluate a haptotherapeutic treatment on the well-being and satisfaction of CPs treated with chemotherapy during day care. Haptotherapy can be seen as a form of complementary care to which touch is central, contributing to the quality of life of patients [31,107].

2.1.1. Procedure

The haptonomic study had a pretest–posttest semi-experimental design, with a separately inclusion of the patients in an intervention and control group. The inclusion for both conditions did not occur at the same time point. Included in the intervention group were patients with cancer of 18 years or older, treated with chemotherapy at the day clinic of the Diakonessenhuis hospital at Zeist, NL. Haptotherapy was offered to all patients during the initial consultation with the oncology nurse. Patients who decided to take up the offer were asked if they were willing to participate in the study. From the nurse they received an introductory letter and the pretest questionnaire. Patients were asked to complete the pretest prior to the first chemotherapy treatment, and if that was impossible, prior to the first corresponding haptotherapy treatment. The five intervention sessions were given during the whole period of chemotherapy. The posttest was handled to the patient by the haptotherapist. This was done at the last or the penultimate

Box 2. Topics for methodological reflections.

(1) Drop-out: Most of the body–mind interventions are experimental studies within going-on patient care, in which patients need not be convinced of the value of the interventions, beside the necessary cooperation of the staff. Due to the drop out, attention to the comparability of the experimental and control groups is required. Not all studies show information about the drop-out and the potential effects of it [27,42,46,47,57,60,66,69,75,76,84,95,96].
(2) C*haracteristics of the participating patients:* Studies are often applied to rather specific groups of CPs, due to the inclusion of the patients. Therefore, demographic and medical characteristics of participating patient groups need to be reported in detail [95].
(3) P*articipation of patients in other complementary interventions:* Given the rising popularity of complementary interventions [4–9,15–20], it is necessary that the studies on the effects of body–mind interventions should be controlled for the use of other related CAM interventions used by patients during the intervention.
(4) The satisfaction of the participants: in general the satisfaction about CAM is high [23,24,95]. Only a few studies report about the satisfaction of the patients with the body–mind interventions [33], while satisfaction may be a prerequisite for finding effects.
(5) Differential effects of interventions: A lot of studies use a combination of relaxation techniques, like visualization, guided imaginary and progressive muscle [33]. This makes it rather difficult to conclude about the specific effects of these interventions. Cassileth and Vickers [65] showed that several types of massage (Swedish massage, foot massage and light touch massage) reduced a variety of symptoms (pain, fatigue, anxiety, nausea, and depression) of a mixed group of in- and out-CPs, with foot massage as the less effective treatment. Only a few studies reported about the specific effects of relaxing face massage as a form of body–mind intervention, although face massage is often may be a part of these massage studies and requiring as body–mind intervention more power and depth than attention to beauty only. [98,99].
(6) Response shift: Due to the experienced intervention, patients may change their norms about their wellbeing before the intervention started this so-called response shift [102,103]. A methodological solution is to measure the pre-test once more after the intervention during the post-measure (retrospective pre-measure or ''then'' protocol). Two studies about psycho-social support groups for CPs confirm these phenomena [1,104].

haptotherapy session. Both questionnaires could be completed at home or in the hospital, and be delivered to the oncology nurse in a sealed envelope or sent to the researcher by post.

The control group consisted of patients from three other hospitals in the Utrecht region, who started there their first chemotherapy treatment. The inclusion of the first control patients started three months after closing the experimental phase. Every patient enrolled in the control group was matched as good as possible to an already known patient in the intervention group with respect to sex, age, type of cancer, type of chemotherapy, evidence of metastasis, prognosis, and the period between pretest and posttest based to the period of the matched intervention patients. Control patients were excluded from the study if they confirmed to use any form of complementary care in which bodily touch was applied.

The patients completed the biographical and medical data by themselves, and if necessary, checked by the oncology nurse in the medical files.

2.1.2. The haptonomic intervention

The intervention consisted of five haptotherapy sessions spread across the period of the chemotherapy. The sessions lasted 45 min each and were carried out in the hospital by two trained, licensed and experienced haptotherapists on days when patients received the chemotherapy. The haptotherapy covers sessions of 45–60 min each, aiming to improve their well-being and coping with the chemotherapeutical treatment. The first session started with a brief introduction by the haptotherapist, asking the patients about their goals. Which techniques the therapist used did depend on the information they gathered during the interview and from the patients' reactions to being touched. By means of the touches, patients learned to focus their attention to particular parts of their bodies and become aware of their feelings. If wished by patients, the treatment became more like a relaxing massage on several parts of their body. Conversation and physical contact are both parts of the treatment. The subsequent four sessions followed the same design. The haptotherapists followed an internal guideline of the hospital. The Medical Ethical Committee (MEC) of the hospital gave permission for the study.

2.2. Relaxing face massage study I for palliative CPs

The objective of this study was to explore the satisfaction with relaxing face massage (RFM) and its effects on the well-being of CPs in the palliative phase of their illness. Face massage can be a part of beauty treatment for CPs, who may suffer from physical changes due to the illness and its treatment [98,33,34,37–39,61].

2.2.1. Procedure

The study was held at the Palliative Care Unit (PCU) and the Radiotherapy Unit AO (RTU) of the AZR/Daniel Clinic, Rotterdam, NL, using a quasi-experimental design. In the first three months, patients were included for the control group. The relaxing facial massage was introduced later and the measures started for the experimental group. The inclusion was open for patients >17 years of age, being able to understand the Dutch language, and mentally able to fill in the questionnaires. The patients were informed by a leaflet and by the nurses in charge. The Medical Ethical Committee (MEC) of the hospital gave permission for the study. The patients filled in and signed a written consent.

During the baseline measures and during the experimental phase, 48 h after admission the patients filled in the questionnaire of the pre-measurement. The post-measure was for the baseline condition seven days after the pre-measurement at the day before or at the day of the discharge (when the stay was shorter than seven days). The post-measure for the experimental group in the hospital was one day after the last RFM. Nurses completed the biographical and medical data.

2.2.2. The relaxing face massage

The RFM was offered between the third and fifth day of the stay, given by a trained, licensed and experienced beauty specialist. RFM treatments lasted about 60 min, performed in the patient's room. The face, neck, head and shoulders were massaged and also eye compresses, and a facial mask were offered. The face was subsequently cleaned and peeled. Expressions of emotions by the patients were discussed. Although each patient received a unique facial massage, the treatments were standardized as much as possible, by focusing on relaxation as the common goal in all treatments. During the study period no other complementary health care activities were provided at the departments. The control patients received care as usual.

2.3. Relaxing face massage Study II for hospitalized and ambulatory CPs

This study aims to determine the evaluation and effects of RFM on the well-being of patients with cancer at two in- and two out-patient units of a cancer clinic.

2.3.1. Procedure

The study has been carried out at the out-patient Chemotherapy Unit (CU) and two clinical units (Radiotherapy unit and Palliative Care and Symptom Control unit) at the Erasmus MC, Rotterdam, the Netherlands. The study is a randomized controlled trial with a control group receiving no RFM and an experimental group receiving two treatments of RFM. The randomization was performed by the trial office of the hospital. The procedure was the same as study I.

Hospitalized patients from the experimental group completed their pre-measurement questionnaire at latest 24 h before the first relaxation treatment, and the post-measurement at latest 12 h after the second treatment. There was at least one day between the two facial massage treatments. Patients in the in-patient control groups were presented the pre-measurement questionnaire immediately after randomization. We aimed to present the post-measurement questionnaire five days later.

At the CU, the first RFM was performed just before the second chemotherapy; the second massage was given just before the third chemotherapy. The experimental group at the CU completed the pre-measurement before the first facial massage, and the post-measurement immediately after the second massage, during the chemotherapy. The out-patient control group completed the first questionnaire during the second chemotherapy and the second questionnaire during the third chemotherapy. Patients from both groups completed in the hospital a pre- and post measurement questionnaire.

During the study period no other complementary health care activities were provided at the departments. After filling in the second questionnaire, patients could ask for the complementary health care offered at the department.

2.3.2. Relaxing face massage

The treatments were given by one of the two trained, licensed and experienced beauty specialists, in service for this study. Both RFM treatments lasted 45–60 min, and were performed in the patient's room or an in separate treatment room. For further details see study I.

Table 1
The questionnaires used in three studies; number of questions and Cronbach's alpha.

Questionnaire	Number of items	Cronbach's alpha		
		Study 1	Study 2	Study 3
Quality of life VAS [1]	1	NA	NA	NA
Quality of life EORTC QLO-C30 [108]	34	NM	NM	NM
Physical functioning	5	0.57	0.77	.71
Role functioning	2	0.69	0.77	NM
Emotional functioning	4	0.79	0.65	NM
Cognitive functioning	2	0.65	0.65	.71
Social functioning	2	0.64	0.77	NM
General quality of life	2	0.76	0.77	.83
Dyspnoea	1	NA	NA	NM
Pain	2	0.80	NM	NM
Fatigue	3	0.86	NM	NM
Insomnia	1	NA	NA	NM
Loss of appetite	1	NA	NA	NM
Nausea and vomiting	2	0.79	0.81	NM
Constipation	1	NA	NA	NM
Diarrhea	1	NA	NA	NM
Mood disturbance POMS [109]	32	0.94	0.95	.93
Meaning in life HDI [1]	4	0.62	0.84	NM
General functioning HDI [104]:	24	NM	NM	NM
Joy of life	15	0.81	0.61	.64[a]
Malaise feelings	9	0.74	0.64	.57[b]
Complaints; De Haes RSC [110]	11		NM	NM
Sleep quality Cox [111]	5	0.82	0.78	.81
Fatigue (VAS) [113]	1	NA	NA	NM
Pain VAS [112]	1	NA	NA	NM
Body awareness/perception Baardman [114]	6	0.74	0.71	.77
Satisfaction with care:				
CSQ [115–117]	8	0.92	0.90	.86
School mark 1–10 [1]	1	NA	NA	NA

NA = not applicable; only one question; NM = not measured.
[a] If question I feel fit has been deleted.
[b] After deletion of 2 items.

2.4. The measures in the three studies

A broad spectrum of physical, emotional and psychological aspects of well-being of the patients was measured in all three studies. Use has been made of existing questionnaires of which the validity and reliability has already been proven in studies into the effects of psychological counseling for people with cancer [1]. Table 1 contains details of all used pre-measures; see too the publications about the three studies [98,99,105,106]. The same questionnaires were used in the posttest. Use of any form of CAM was based on a questionnaire developed by Van Delft et al. [118].

Except for the measurement of the physical functioning of the EORTC, the alpha's are above .60 and varying between 0.57 and 0.92. In the third study the alpha's were lower than .60 for joy of life and malaise, but higher in the post-measures. Especially in the third study the length of the questionnaire was reduced using only core questions.

3. Results of the three studies

3.1. Participation and drop out

The three studies contained in total 267 CPs. From them 40% did drop-out of the studies. Based at the data in Table 2 the dropout is higher in the experimental groups than in the control groups, except for the third study. This last study was the most controlled study, strictly guided by the trial office and supervised by the researcher. Based on the drop-out, patients seem more willing to fill in a questionnaire than accepting the offered intervention.

The main reason for the drop-out in the intervention groups was the mental and physical condition of the patients, leading to refuse to fill in questionnaires in the post-measures, which caused incomplete data sets.

3.2. Patient characteristics

The results in Table 3 show that the three samples are rather comparable. The number of breast cancer patient is lower in the samples of the last two studies due to the fact that departments with several types of CPs were involved in the studies. In the first study the number of patients with metastases is lower than in the two other studies because the last two studies were performed in

Table 2
Participation and non-response data in the three studies.

	HAPTM		FACERM I		FACERM II	
	Contr	Exp	Contr	Exp	Contr	Exp
Participant at inclusion	35	55	33	41	53	50
Completed data sample	26	31	15	19	36	43
	74.4%	56.4%	45.5%	46.3%	67.9%	86.0%
Total drop out						
Reasons for drop-out	9	24	18	32	17	7
Not interested, refusal before start	0	0	0	7	N	N
Participated in another intervention	3	1	0	0	0	0/
Changing medical treatment/condition	1	2	0	2	N	N
Refused during intervention	0	1	15	18	N	N
Questionnaires lost in mail	4	2	0	0	0	0
Too ill, mentally not able	1	2	3	5	0	o
Passed away	0	6	0	0	0	0
Unknown	0	9	0	0	0	0

HAPTM = Haptotherapy study; FACERM I = Relaxing face massage study I; FACERM II = Relaxing face massage study II; Contr = control group; Exp = experimental group; N = unknown.

Table 3
Demographic and medical characteristics at the pre-measurement.

	HAPTM	FACERM I	FACERM II
Sample size	57	34	103
Age (mean years)	53.4	54.2	55.1
Gender: female	77.2%	64.7%	70.1%
Married/living together	86.0%	76.5%	NM
Still child(ren) at home	28.5%	14.7%	NM
Social economic status (SES)[a]			
Low	28.8%	17.6%	NM
Middle	47.4%	58.8%	NM
High	29.8%	23.5%	NM
Metastases	59.6%	79.4%	69.2%
Type of cancer			
Breast cancer	49.1%	32.4%	25.3%
Intestinal	24.6%	11.8%	15.2%
Others	26.3%	55.8%	59.5%
Treatment			
Surgery	80.7%	64.7%	65.7%
Radiation	28.0%	79.4%	75.5%
Hormonal therapy	27.8%	17.6%	22.5%
Chemo-therapy	100%	61.8%	77.5%

Note: HAPTM = Haptotherapy Study, FACERM I = Relaxing face massage study I, FACERM II = Relaxing face massage study II; NM = not measured.
[a] Based at a sum score of education, job status, and income level [26].

an academic hospital, which often attracts the more severe ill patients.

The control group in the first study only contained more patients with still a child at home than the intervention group ($p = .03$). However, this variable was not related with the dependent variables. In the RFM study I the intervention patients staid longer in the hospital when they filled in their first questionnaire than the control group ($p = .02$), which was either with the dependent variables. In the RFM study II, the experimental groups of the in-patient units had more often a partner and did contain less women than in the control groups (both $p = .04$), also not related with the dependent variables. The out-patient experimental groups were hospitalized more often in the past than the control group ($p = .03$). Because this factor was related to several base-line variables, a correction for hospital admissions has been made in the analysis of variance for the effects of the intervention.

3.3. Participation in other complementary interventions

Across the studies it was checked if other forms of complementary interventions were used or offered. In the intervention and control group of the haptotherapy study the use of haptotherapy outside the study was banned on request, and was an exclusion criterion. However, patients from the intervention and control group answered in the pre-measurement questionnaire that they ever in their life (often plus sometimes) used haptotherapy, massage, relaxation therapy, beauty treatment, sauna, or Reiki; this were 29 patients who used one or more of 40 treatments. In the post measurement only two patients (7.7%) within the control group answered that they used some form of the before mentioned care forms.

The data of the RFM I show at the pre-measurement that within the intervention and control groups 30 patients did ever use in their life one or more of 40 of the before mentioned treatments. The existing massage and aromatherapy at the department were official stopped for the experimental and control group. However, in the pre-measurement 47.5% patients of the intervention group answered that they use massage since the admission; nobody used aromatherapy. In the control group 13.3% of the patients used massage as well as 13.3% aromatherapy. This practice was changed in the RFM II; outside the face massage, no other massages of aromatherapy was offered and accepted.

3.4. Satisfaction with the interventions

Patients are highly satisfied with the three types of body–mind interventions. Using a scale of 1–10, the mean scores are between 8.4 and 8.6 (see Table 4). Also the mean scores on the Client Satisfaction Questionnaire (CSQ) are high for the three studies. They confirm that in answers on open questions about their evaluation [98]:

> "A very relaxing moment, you forget why you are in the hospital, release of the stress in my body, feel me more a human being than a patient only, the feeling that there is more in this world than your illness".

3.5. Effects of the interventions

The results of the analysis of the effects of the three interventions are presented in Table 5. Further details are published elsewhere [98,99,105,106]

The haptotherapy intervention shows initially effects on several dependent variables. There is an increase in role, emotional, and social functioning; further there is a decrease in pain, loss of appetite, malaise feeling, general complaints, depression, and stress. In a multivariate analysis several factors were controlled, showing only an increase on the two measures of general quality of life, the cognitive, and the social functioning.

The second study on relaxing face massage showed in first instance an increase of cognitive functioning, and a decrease of physical complaints, nausea, lack of appetite, mood disturbance, depression, stress, two measures of fatigue, and pain. This picture changes radically in the multivariate analysis: only one measure of fatigue is decreasing.

For the third RFM study we will not report the differences between the studied in- and out-patient groups. These differences were rather small and specific, and do not contribute to the evaluation of the study, as reported elsewhere. [99]. The comparison of the pre-and post measures shows an increase in physical functioning, and a decrease of malaise feelings, general complaints, mood disturbance, depression, stress, two measures of fatigue, and pain. However, the multivariate analysis reveals a decrease in pain and anger only.

3.6. Response shift

In the RFM I study the retrospective measures of Joy of life and Malaise were applied. The results are presented in Table 6.

Within the intervention group the pre- and post-measures of Joy in life were not significant different. However, the difference between the retrospective and the post-measure is statistically significant ($p = .02$). This is not the case for the Malaise measure. Within the control group, however, the retrospective measurement of the malaise is lower than in the pre-measurement, but not significantly ($p = .09$). The same results were found for the response shift in the second RFM study.

Table 4
Patient satisfaction with the interventions.

		HAPTM	FACERM I	FACERM II
School mark (1–10)	Mean	8.4	8.6	8.5
	Range	6–10	7–10	6–10
CSQ (1–4)	Mean	3.6	3.5	3.6

Note: HAPTM = Haptotherapy Study, FACERM I = Relaxing face massage study I, FACERM II = Relaxing face massage study II.

Table 5
Effects of the three interventions (see Table 1 for explanation of the measures).[a]

	HAPTM[b]		FACERM I[c]		FACERM II[d]	
	Pre–post ex	Mult. test	Pre–post ex	Mult. test	Pre–post ex	Mult. test
General quality of life (VAS)	=	>	NM	NM	NM	NM
Aspects of quality of life (EORTC) [21]						
General quality of life	=	>	=		=	
Physical functioning	=		<		<	
Role functioning	>		=		=	
Emotional functioning	>					
Social functioning	>	>	=		=	
Cognitive functioning	=		>	>	=	
Fatigue	=		=		<	
Pain	<	NM	NM	NM	NM	NM
Sleeping	=	NM	NM	NM	NM	NM
Lack of appetite	<		<		=	
Nausea	=		<		=	
Constipation	=		=		=	
Diarrhea	=		=		=	
General functioning (HDI) [23]						
Joy of life	=		NM		=	
Malaise feelings	<		NM		<	
General complaints RSC [24]	<		NM		<	
Mood disturbance (POMS) [22]						
Total score	=		<	<	<	
Depression	<		<		<	
Stress	<		<		<	
Fatigue	=		<		<	
Anger	=		<	<	<	<
Vigor	=		=		=	
Body image/perception [19]	=		=		=	
Pain (VAS) [37]	NM		<		<	<
Sleep quality (Cox) [20]	=		=		=	
Fatigue (VAS)	NM		<		<	
Meaning of life (HDI) [18]	=		=		=	

Note: HAPTM = Haptotherapy Study, FACERM I = Relaxing face massage study I, FACERM II = Relaxing face massage study II; NM = not measured. =: means no change; >: means increased; <: means decreased.

[a] Empty cells in Mult.test means no changes.

[b] Pre–post test experimental group: Wilcoxon Signed Rank Test; multivariate analysis: linear regression analysis and logistic regression analysis; controlling for children at home, time period between pre–post measure, the period between the first and last haptotherapy session varied between three and 36 weeks, with an average of 115 (SD = 6.5) and score on the pre-measurement; $p < 0.05$.

[c] Pre–post test experimental group: Wilcoxon Signed Rank Test; multivariate analysis: ANOVA repeated measures; $p < 0.05$.

[d] Pre–post test experimental group: Wilcoxon Signed Rank Test; multivariate analysis: ANOVA repeated measures; controlling for previous hospital admissions; $p < 0.05$.

4. Discussion and conclusion

We will discuss the six presented methodological reflections, and conclude on a more general level, and discuss the implications and recommendations for the practice of conducting studies with similar intervention in hospitals.

4.1. Discussion

4.1.1. The drop-out

All the three studies suffered from a substantial dropout. Across the studies the drop-out was 40%. This is higher comparable with other studies [77], but also lower than in other studies [33,34,37,39,41,61]. We were not able to send patients reminders due to the anonymity of their participation, a method which could have increased the response [119]. We compared the drop-outs during the study with the patients who completed the study, based on the pre-measures. These differences were absent or small. This means that the results of the studies may not be influenced by the drop-out and that the conclusions do not only apply to specific groups of CPs only.

CPs are often rather ill, suffering physically and mentally, causing that patients stopped during the intervention. Filling in long questionnaires is a burden for CPs. This was for them too a reason to stop the active participation in the studies. Further, to rely in the studies on nurses means extra work for them. Learned from both former studies, we more intensively supervised the 3e study, leading to a lower drop-out rate.

Table 6
Retrospective pre-measures on Joy of life and Malaise feelings (FACERM I).

	Control groups			Intervention groups		
	Pre-measure	Post-measure	Retrosp. measure	Pre-measure	Post-measure	Retrosp. measure
Joy of life	16.5 (3.8)	16.7 (4,23)	14.9 (4,1)	16.1 (4.2)	16.8 (3.6)	15,6 (4.2)*
Malaise: M (SD)	24.6 (4.7)	22.9 (5,4)	20.9 (6.1)**	23.6 (5.8)	24.9 (6.3)	24.5 (7.0)

* Comparison of retrospective pre-measure with post-measurement: $p = 0.02$ (Wilcoxon test).

** Comparison of retrospective pre-measure with pre-measurement: $p = 0.09$ (Wilcoxon test).

4.1.2. The characteristics of the patients

The participants are mainly women with breast cancer, who followed a higher education, which is often the case in psychosocial interventions for CPs [1–3,120–122]. The relaxing face massage study I contains patients who are more severe ill; 79% of the patients report having metastases. This may have caused the high drop-out, although the reported effects are not different from both other studies. We found only a very few and statistical differences concerning characteristics of the patients the experimental and the control groups. These variables were not related to the dependent variables, except for the number of previous hospital admissions. All mentioned characteristics were introduced as control variable in the final multivariate analyses, a procedure not always applied in studies on body–mind interventions [33,34,37–39,61]. These results implicate that the comparison of the effects on body–mind interventions for CPs will be based on comparable groups.

4.1.3. Participation in other complementary activities

The first two studies show that the patients were not only exposed to the planned interventions, but also to other forms of body–mind activities. This may have strengthened the effects of the interventions in the experimental group. This may mask the specific studied effects of the intervention. The patients in the control groups in both first studies were very much restricted in their participation in other body–mind interventions. In the third study we were able to stop the offer of other body–mind activities by a strict change in the policy of the department. Based on our results and other reviewed studies [33,34,37–39,61] we would like to advice to check in all intervention studies the exclusion of the use other CAM consumptions by the patients.

4.1.4. The satisfaction of the patients

The patients are very satisfied about the intervention. This is an important prerequisite for finding effects. In a cross-sectional study we found that the satisfaction of patients with complementary approaches may lead to a higher quality of life, supposing that the complementary approaches had a meaning for the patients [97]. The levels of satisfaction are comparable with other Dutch studies on psychosocial care for people with cancer [1,120,121,123]. The risk of bias due to social desirability was reduced by collecting the questionnaires by mail, nurses and the researchers rather than by the therapists. In other studies among CPs the satisfaction measures were not correlated with the social desirability measure [121]. Extra attention was given to the patients, which may be appreciated and could have influences the effects [33,34,37–39,61]. We should accept that attention is an active ingredient in body–mind interventions, strengthening the effects.

4.1.5. The effects of the interventions

The effects of the interventions are rather limited. Other studies found an improvement in quality of life and a reduction of pain, stress, anxiety, vomiting/nausea, and sleeping problems, fatigue as shown in reviews [33,34,37–39,61] and studies [22,26,28–30,34,35,37–50,52–60,63,66,70,70–79,83–89,102,124]. The study I on Relaxing Face Massage showed only effects on fatigue. This may be explained by the fact that the study was at the Radiotherapy department where the CPs may suffer more from fatigue than at other departments. Also Decker at al. [66] found significant effects on fatigue of relaxation therapy for radiology patients. Two other studies reported effects on fatigue, applying a back massage [60] and stress management training [40].

The number of RCT's on CAM interventions is growing [92]. Applying to our studies, only the third study has this optimal design. We found a decrease in anger and pain. This is confirmed by a study of Snyder et al. [125] showing a decrease in agitation by hand massage for persons with dementia. Effects on pain are very common in massage studies [22,26,34,35,38,39,43,44,46,47,55–57]. We did not find effects on measurement of Malaise feelings; absence of effects on negative feelings has been reported in other studies [52,58,59].

A limitation is that the reported effects are based at the subjective well-being of the patients. Information about the observed quality of the patient–therapist interaction is not available. This would have been an important source of information for the explanation of the found effects, as was reported in communication in health care studies [126].

The interventions were bodily oriented, which is a reason that we measured the body perception by the patients. The interventions did not influence the evaluation of the body and its perception. We like to stress that the interventions were short, especially in the two studies on relaxing face massages. In the haptotherapy study the patients underwent five massages, which may explain finding more effects. Also studies elsewhere used short term intervention, like during two days 30 min [27], 10 or 30 min foot massage [41,42]; 10 min back massage [43], and three times a week 20 min [124]. These studies report effects, using not optimal designs. Other studies applied longer term interventions of several massages during three weeks or weekly during four weeks [30,61], reporting reduction of complaints, increasing emotional well-being, and spirituality. In reviews several effective long term studies are presented [33,34,37,39].

In the two relaxing face massage interventions, the well-being was not measured directly after the massages. Wilkie et al. [44] reported in a study on palliative patients that two massages during two successive weeks did not show long give effects, but measures direct after the massage did lower the pain. The time between intervention and the post-measure may have been too long in our studies.

4.1.6. The role of response shift

In two studies we found that the feeling of Joy in life was lower in the retrospective pre-measure than in the real pre-measure. This perceived lower level of feeling of Joy did lead to a significant difference in comparison with the post-measure, as also demonstrated in studies on the effects of therapy groups for CPs [1]. This was not the case in the control group and also not for the feeling of Malaise. A retrospective improvement in Joy of life has also been. It is important to note that especially the perception of positive feeling may be influenced by the experienced face massages. CPs may have realized that, when these touched has happened, that they were more suffering than they thought before the intervention. It is not possible to repeat the whole pre-measure as a retrospective measure. That would be too burden for the patients. It would be important to explore more evidence for the masking effect of response shift in complementary medicine approaches and to develop standardized tools to take in account response shift.

4.1.7. Relevance and application for health communication research

Body–mind approaches need its own place in the development of communication in healthcare, requiring a more identifiable place in the interventions and training to improve the well-being of CPs. Studies on body–mind interventions need more methodological reflections in order to develop effective interventions and adequate study designs. Attention should be given to invent strategies to involve more patients in interventions, to reduce the drop-out in studies. It needs long term studies, applying several body–mind interventions. More evidence should be presented about the effects of sound studies, in order to convince HCPs (medical doctors, leading nurses) to accept complementary approaches. Within the care, also practical short term interven-

tions should be developed and evaluated. More observational research is necessary to explore promising interventions.

4.2. Conclusions

Body–mind interventions require more methodological reflections to develop attractive and effective interventions for CPs. Attention need to be paid to measuring short term effects, practically fitting research designs, and response shift. They are mainly the small sample sizes, the low intensity of the intervention, the possible inadequate measure moments and the use of other CAM that may be responsible for the absence of effects.

4.3. Practice implications

Body–mind interventions are appreciated by CPs; they compensate the lack of attention to body-touch during their illness and its treatment. It would be import to offer such body–mind interventions to more cancers patients. The implementation of effective body–mind interventions requires attention to the implications for the organization of the care: the management and physicians need to agree with the introduction of the interventions, a person at the department should be responsible for it, it needs a budget, there should be a trained and licensed therapist or a trained HCP, there should be time and a place to offer it to the CPs.

Conflict of interest

We confirm that all patient/personal identifiers have been removed or disguised to ensure anonymity of all patients/persons described. The authors indicated no potential conflict of interest.

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