

分担研究報告書

海外の妊孕性温存における心理社会的体制の情報収集

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研究要旨

アメリカ合衆国イリノイ州シカゴに拠点をおく Oncofertility Consortium の年次集会に 2014 年から 2016 年まで 3 年間参加し、アメリカのがん・生殖医療における心理社会的システムの情報収集をおこなった。アメリカでは心理士または心理専門職がケアの中心となっていて、施設の他職のスーパーバイズをおこないつつ、がん・生殖医療を希望する患者のカウンセリングを自ら実施していた。他の国では、心理士が施設にいるかどうかによって依存していた。

ヨーロッパは世界生殖学会、ヨーロッパヒト生殖学会心理学グループ、国際不妊カウンセリング協会に参加して心理社会的ケアの情報収集をおこなった。がん・生殖医療に携わる心理士はととも少なかった。

がん・生殖医療における心理社会的ケアは心理専門職の有無によること、心理専門職が提供する内容は心理専門職のスキルに依存していることが示唆された。

A. 研究目的

国外で妊孕性温存における心理支援体制をどのように整えているのかについて、学会参加を通して情報収集した。

B. 研究方法

a) アメリカの状況について

Oncofertility Consortium が主催した 2014 Oncofertility Conference, 2015 Oncofertility Conference, 2016 Oncofertility Conference に参加し、アメリカを始めとする妊孕性温存における心理社会的ケアの状況について情報収集した。また、Global Meeting への参加を許されて、3 年間で世界各国の心理社会的ケアの情報収集もおこなった。

b) ヨーロッパの状況について

世界生殖学会 World Congress of Human Reproduction 2015、国際不妊カウンセリ

ング協会 (International Infertility Counseling Organization)、ヨーロッパヒト生殖学会 (European Society of Human Reproduction and Endocrinology; 以下 ESHRE) に 2016 年参加した。

C. 結果

a) アメリカの状況について

Oncofertility Consortium はアメリカ合衆国イリノイ州シカゴにある Northwestern 大学医学部産婦人科 Teresa Woodruff 教授が主宰している国際学会で設立 10 年である。

2014 Oncofertility Conference, 2015 Oncofertility Conference, 2016 Oncofertility Conference に参加し、本研究班の臨床試験について学会発表をおこなった (資料 6-1, 2, 3)。がん・生殖医療の心理カウンセリングは定型がないため、注目を浴

びた。

アメリカでは、心理士が心理社会的ケアの中心となっていて、施設の患者ナビゲーターなど他職のスーパーバイズをおこなったり、がん・生殖医療を希望する患者のカウンセリングを実施していた。具体的な心理カウンセリングについては、がん・生殖医療における6つの要点を掲げた。

日本はGlobal Partner っている関係で、Global Meeting への参加を許されており、3年間で世界各国の心理社会的ケアの情報収集もおこなった。その結果、

心理士がいない国・施設（多くの国）はソーシャルワーカー、医師が担当するか、誰も心理社会的ケアを担当しないという状況であった。その他の国では心理士がほとんど関わっておらず、多職種連携は活発ではないとわかった。

b) ヨーロッパの状況について

世界生殖学会 World Congress of Human Reproduction 2015、国際不妊カウンセリング協会 (International Infertility Counseling Organization)、ヨーロッパひと生殖学会 (European Society of Human Reproduction and Endocrinology; 以下 ESHRE) に2016年参加した。

世界生殖学会では心理士の参加がなかった。イタリア、ドイツの医師からは、生殖専門施設には常駐する心理士はいなくて、地域やプライベートの心理カウンセリングにかかるのが一般的だとわかった。

国際不妊カウンセリング協会、ヨーロッパひと生殖学会では、心理職に多数あったが、生殖専門施設、総合病院、開業カウンセラーのどこにおいても若年がん患者がほとんどいないことがわかった。

唯一、スイス（フランス語圏）の心理士ががん・生殖医療に関心が深い医師とともに

に取り組んでいたが、症例数は少なかった。

D. 考察

海外視察を通して、がん・生殖医療における心理社会的ケアは担当者の有無に依存することがわかった。

つまり、日本以外の国では、施設内に心理士または心理専門職（先進国では心理療法の訓練を受けたソーシャルワーカー、セラピスト）がいる場合は心理社会的ケアを提供していた。しかし、心理専門職がいなければ、他職が職域を越えて担当することはせず、通常診療において患者の心理面に配慮したコミュニケーションをする中で何かリスクがあれば専門家に紹介するという流れであった。職域が明瞭であり、専門家が相互に独立した存在であると言える。

これに対して日本は、心理専門家でなくても心理面のケアやカウンセリングを担当している場合がある。患者の医療情報や気持ちを整理する場合は心理専門職でなくてもできる部分があるが、対人関係調整や心理カウンセリング、危機介入などは専門的訓練の欠如で困難に陥ることもある。

E. 結論

アメリカの Oncofertility Consortium、ヨーロッパの世界生殖学会、国際不妊カウンセリング協会、ヨーロッパひと生殖学会に参加して、がん・生殖医療における心理社会的ケアは心理専門職の有無によること、心理専門職が提供する内容は心理専門職のスキルに依存していることが示唆された。

F. 健康危険情報

なし

（分担研究報告書には記入せずに、総括研究報告書にまとめて記入）

G. 研究発表

1. 論文発表

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小泉智恵・高見澤聡・平山史朗・奈良和子・上野桂子・宮川智子・橋本知子・山崎圭子・杉本公平・鈴木直・森本義晴. 2015 生殖心理カウンセラーによるがん・生殖医療外来の陪席：混合研究法による女性がん患者の否定的感情の表出と心理支援の可能性の関連. 日本生殖心理学会誌;1:2;46-54.

2. 学会発表

Tomoe Koizumi, Chie Nishijima, Yodo Sugishita, Keiko Ueno, Noriko Hiraki, Kazuko Nara, Shiro Hirayama, Tomoko Miyagawa, Tomoko Hashimoto, and Nao Suzuki. 2014 The Oncofertility! Psycho-Education And Couple Enrichment therapy (O!PEACE): An intervention study protocol for a randomized controlled trial in Japan. 2014 Oncofertility Conference, Chicago, IL, U.S.A.

Tomoe Koizumi, Chie Nishijima, Seido Takae, Kazuko Nara, Tomoko Miyagawa, Misako Nakajima, Keiko Ueno, Chiaki Hoshiyama, Kouhei Sugimoto, and Nao Suzuki. 2015 Examining fidelity of the Oncofertility! Psycho-Education And Couple Enrichment (O!PEACE) therapy for the young breast cancer patients and their husbands. 2015 Oncofertility Conference, Chicago, IL, U.S.A.

Tomoe Koizumi, Chie Nishijima, Kazuk

o Nara, Tomoko Miyagawa, Misako Nakajima, Kouhei Sugimoto, Tatsuro Furui, Yasushi Takai, Hiroshi Matsumoto, Hideko Yamauchi, Shinji Ohno, Akemi Kataoka, and Nao Suzuki. 2016 Oncofertility! Psycho-Education And Couple Enrichment (O!PEACE) therapy: the progress report of the randomized control trial in Japan. 2016 Oncofertility Conference, Chicago, IL, U.S.A.

小泉智恵 新しい心理社会的ケアの在り方：多職種が様々なレベルで. 2017 第14回日本生殖心理学会学術集会・招待講演.

H. 知的財産権の出願・登録状況 (予定を含む。)

1. 特許取得

なし

2. 実用新案

なし

3. その他

なし

The Oncofertility! Psycho-Education And Couple Enrichment (O! PEACE) therapy: An intervention study protocol for a randomized controlled trial in Japan

Tomoe Koizumi¹, Chie Nishijima², Yodo Sugishita², Keiko Ueno³, Noriko Hiraki⁴, Kazuko Nara⁵, Shiro Hirayama⁶, Tomoko Miyagawa⁷, Tomoko Hashimoto⁸, and Nao Suzuki²

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Background

ASCO 2013 Guideline gives health care providers the recommendation for referring cancer patients or survivors to psychosocial providers (i.e., in Japan, certified clinical psychologist with certified infertility psychological counselor) if they experience distress about potential infertility (Loren, 2013).

When the patients are informed by their doctors that they have suffered from cancer, most of all could be upset and could not consider their purpose of life and their fertility concerns. Many studies reported most cancer patients had severe depressive symptoms and PTSD symptoms for several months from the cancer diagnosis (e.g., Yin-Raviv, 2013). In Japan, the cancer experience means a severe psychological stressful process for the patients. The risks of suicide within the first year after a cancer diagnosis were extremely higher than those among cancer-free population (the adjusted RRs: 23.9; 95%CI: 13.8-41.6) (Yamauchi, 2014).

Many studies of these systematic review reported that semi-structured psycho-educational therapy decreased psychological distress in early stage of cancer (e.g., Fawzy, 1994). Psycho-educational therapy means one of psychotherapies focused on the improvement of stress coping strategies, interpersonal communication and relationships.

The patient's experience of cancer could be a crucial influence on partners' emotional life and well-being. In general, many partners take an active role in key decisions concerning treatment options and provide emotional and instrumental support to the patient. The meta-analysis study indicated that there is a moderate correlation between distress in persons with cancer and their partners' distress (Hagedoorn, 2008).

Couple therapy, however, is effective for cancer patients and spouses in order to improve their mental illness and marital communications. Depressive symptoms with both cancer patients and their partners were decreased by the couple therapies (Manne, 2005; McLean, 2007).

Purpose

The aim of this study is to examine whether the psychotherapy can reduce concerns of fertility and psychological distress, and improve marital communication with cancer patients and their partners. We conduct the Oncofertility-related Psycho-Education and Couple Enrichment (O!PEACE) therapy.

Hypotheses

First, we hypothesized that the impact of O!PEACE therapy on their distress, mental health and marital communication could be mediated by their stress coping strategies and resilience. O!PEACE therapy could also improve stress coping strategies and resilience directly.

Second, we hypothesized that receiving O!PEACE therapy could ameliorate the couple's concerns of fertility, better mental health and marital communication rather than reading the booklet of Psycho-Education and Couple Enrichment (Booklet of O!PEACE).

Third, we also hypothesized that O!PEACE three session could be the most effective of all three courses.

Systematic review

	Neoplasms X Psychotherapy	Reproductive Techniques X Psychotherapy	Neoplasms X Reproductive Techniques	Neoplasms X Reproductive Techniques X Psychotherapy
PubMed	3073	142	3168	1
J ECT	543	13	214	0
Age 17-44	327	12	161	0
Published within 10 years	229	10	125	0
Psychology	167	4	11	0
The Cochrane Library	647	15	297	0
Cochrane Reviews	14	0	12(b)	0
PsychINFO (Urban&Schwarzenberg)	178	3(c)	8	0
Review articles	31	1	2	0

(a) We searched on July, 2014. We used the relevant terms referenced from MeSH or Thesaurus.

(b) Only two articles deal with the fertility problems with cancer patients.

(c) Four articles of nine were written in French or Spanish.

We tried the systematic review about psychotherapies of concerns of fertility or psychosomatic symptoms among cancer patients. In July 2014, we searched the PUBMED, The Cochrane Library, and PsychINFO. The results are shown at above the table. The number of articles on psychological intervention of oncofertility were little, whereas huge articles on psychological intervention among cancer patients.

Method

O!PEACE the Oncofertility! Psycho-Education and Couple Enrichment therapy, is a goal to calm down their upset feeling, reconsider their life and fertility, and regain their mental health and psychological growth. O!PEACE therapy is a short-term approach based on solution-focused therapy and couple & family therapy with stress coping skill and assertive communication skill training.

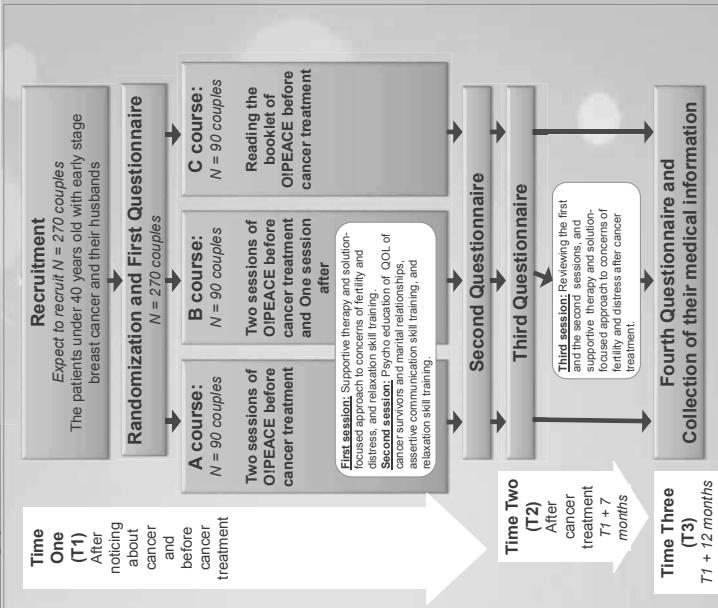
Well-trained certified clinical psychologists specialized on fertility will conduct the O!PEACE therapy until before first cancer treatment. We will conduct the randomized controlled trials for early stage breast cancer patients and their partner (n=270 couples).

The couples will be randomized into three intervention groups: either the O!PEACE therapy twice group (A course), the O!PEACE therapy three times group (B course), or the booklet of O!PEACE group (C course). The couples will participate in one of three intervention groups and pre-post questionnaires.

The main outcome variables are mental health (HADS, K6, IES-R), well-being (WHO-Five Well-Being Scale, PG1) and marital relationships (Marital Relationship Scale, Scale of Relationship-Focused coping). The parameters are stress coping strategies (TAC-24) and resilience (CD-RISC). In Japan, top three or more hospitals in which both breast cancer treatment and fertility treatment will conduct this study.

The authors have no conflict of interest to disclose with respect to this presentation.

Study protocol



Discussion

O!PEACE therapy has potential as an accessible and acceptable intervention for cancer patients and their partners. To our knowledge, this study will be the first RCT to investigate the efficacy of a O!PEACE treatment program for breast cancer patients and their partners.

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This work was supported by Health Labour Sciences Research Grant #H26-Cancer-017 (The Ministry of Health Labour and Welfare).

Examining Fidelity of The Oncofertility! Psycho-Education And Couple Enrichment (O! PEACE) therapy for the young breast cancer patients and their husbands

Tomoe Koizumi¹, Chie Nishijima², Seido Takae², Kazuko Nara³, Tomoko Miyagawa³, Misako Nakajima⁴, Keiko Ueno⁵, Chiaki Hoshiyama⁶, Kouhei Sugimoto⁷, and Nao Suzuki²

¹National Research Institute for Child Health and Development, ²St. Marianna University School of Medicine, ³Kameda Medical Center, ⁴Kiba Park Clinic, ⁵Ohita Prefecture Infertility Specialty Counseling Center, ⁶Counseling room Flat, ⁷The Jikei University School of Medicine



Background

When the patients are informed by their doctors that they have suffered from cancer, most of all could be upset and could not consider their purpose of life and their fertility concerns. Many studies reported most cancer patients had severe depressive symptoms and PTSD symptoms for several months from the cancer diagnosis (e.g., Yin-Raviv, 2013).

Many studies of these systematic review reported that semi-structured psycho-educational therapy decreased psychological distress in early stage of cancer (e.g., Fawzy, 1994). Psycho-educational therapy means one of psychotherapies focused on the improvement of stress coping strategies, interpersonal communication and relationships.

The patient's experience of cancer could be a crucial influence on partners' emotional life and well-being. In general, many partners take an active role in key decisions concerning treatment options and provide emotional and instrumental support to the patient. The meta-analysis study indicated that there is a moderate correlation between distress in persons with cancer and their partners' distress (Hagedoorn, 2008).

Couple therapy, however, is effective for cancer patients and spouses in order to improve their mental illness and marital communications. Depressive symptoms with both cancer patients and their partners were decreased by the couple therapies (Manne, 2005; McLean, 2007).

Thus, we conducted to make the effective psychological therapy for cancer patients in fertility preservation settings. We made originally the psychological therapy for cancer patients and their spouses: The Oncofertility! Psycho-Education And Couple Enrichment (O! PEACE) therapy (Koizumi, 2014; 2015).

Purpose

The aim of the study is

- I. To make the effective psychological therapy, the O! PEACE therapy, and
- II. To examine the efficacy of the psychological intervention for cancer patients in fertility preservation settings.

We will conduct the O! PEACE therapy to young (≤ 39) breast cancer patients and their husbands until before first cancer treatment. Whoever know the fertility preservation or not can receive the O! PEACE therapy.

Contact us: Tomoe Koizumi, Ph.D. E-mail: koizumi-t@ncchd.go.jp

This work was supported by Health Labour Sciences Research Grant #126-Cancer-017 (The Ministry of Health Labour and Welfare).

The authors have no conflict of interest to disclose with respect to this presentation.

I. Making the O! PEACE therapy

The O! PEACE, the Oncofertility! Psycho-Education and Couple Enrichment therapy, is a goal to calm down their upset feeling, reconsider their life and fertility, and regain their mental health and psychological growth.

The O! PEACE therapy is a short-term approach based on solution-focused therapy and couple & family therapy. It consists of two sessions. It takes about 70 minutes per a session.

The contents of the in-depth manual of the O! PEACE therapy is follows;

1. Psycho-education of oncofertility
2. Supportive therapy of life and fertility crisis
3. Solution-focused approach to distress of cancer and fertility
4. Relaxation skill training
5. Assertive communication between couple

O! PEACE First Session (Date)

How do you feel (unwellness or anxiety) now?
Please evaluate it with ten points from a score zero
Wife / H. Husband / O! PEACE

Let's do the following things!

- 1. Psycho-education of oncofertility
- 2. Supportive therapy of life and fertility crisis
- 3. Solution-focused approach to distress of cancer and fertility
- 4. Relaxation skill training
- 5. Assertive communication between couple

Let's do the following things!

- 1. How do you feel about your partner's cancer?
- 2. How do you feel about your partner's fertility?
- 3. How do you feel about your partner's life?
- 4. How do you feel about your partner's future?
- 5. How do you feel about your partner's relationship with you?
- 6. How do you feel about your partner's relationship with his/her family?
- 7. How do you feel about your partner's relationship with his/her friends?
- 8. How do you feel about your partner's relationship with his/her community?
- 9. How do you feel about your partner's relationship with his/her society?
- 10. How do you feel about your partner's relationship with his/her world?

Let's do the following things!

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- 1. How do you feel about your partner's cancer?
- 2. How do you feel about your partner's fertility?
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- 4. How do you feel about your partner's future?
- 5. How do you feel about your partner's relationship with you?
- 6. How do you feel about your partner's relationship with his/her family?
- 7. How do you feel about your partner's relationship with his/her friends?
- 8. How do you feel about your partner's relationship with his/her community?
- 9. How do you feel about your partner's relationship with his/her society?
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Let's do the following things!

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- 1. How do you feel about your partner's cancer?
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- 8. How do you feel about your partner's relationship with his/her community?
- 9. How do you feel about your partner's relationship with his/her society?
- 10. How do you feel about your partner's relationship with his/her world?

II. Examining the efficacy of the O! PEACE therapy

We examined the efficacy of the O! PEACE therapy as follows;

- i. Training four psychologists who can provide O! PEACE therapy
 - ii. Recording the trial sessions of the O! PEACE for each psychologists
 - iii. Evaluating these records by two supervisors
 - iv. Calculating the inter-rater agreement
- i. Four certified fertility reproductive psychologists finished 16 times of roll-playing training course of the O! PEACE therapy. They could perform it substantially.
 - ii. We recorded the last roll-playing training session of all psychologists. It took about 140 minutes per a psychologist.
 - iii. Two supervisors who are skillful reproductive psychologists evaluated whether they performed exactly and adequately watching all records respectively.
 - iv. We calculated the inter-rater agreement using Kappa coefficient. The results are as follows;
K= .778-. 949 for each psychologists
K= .856 for all contents of the therapy

The some scenes of training sessions of the O! PEACE therapy



Conclusions

Based on the level of adherence to the O! PEACE therapy, the treatment integrity can be judged as high. We concluded the O! PEACE therapy indicated the excellent level of the reliability and the validity. Now, we have conducted the RCT study using the O! PEACE therapy.

To be continued next year!

The Oncofertility! Psycho – Education And Couple Enrichment (O! PEACE) therapy: The progress report of the randomized control trial in Japan

Tomoe Koizumi¹, Chie Nishijima², Kazuko Nara³, Tomoko Miyagawa³, Misako Nakajima⁴, Kouhei Sugimoto⁵,
Tatsuro Furui⁶, Yasushi Takai⁷, Hiroshi Matsumoto⁸, Hideko Yamauchi⁹, Shinji Ohno¹⁰, Akemi Kataoka¹⁰, and Nao Suzuki²
¹National Research Institute for Child Health and Development, ²St. Marianna University School of Medicine, ³Kiba Park Clinic, ⁴Kiba Park Clinic, ⁵The Jikei University School of Medicine
⁶Gifu University, ⁷Saitama Medical University, ⁸Saitama Cancer Center, ⁹St. Luke International Hospital, ¹⁰The Cancer Institute Hospital of JFCR



Background

When the patients are informed by their doctors that they have suffered from cancer, most of all could be upset and could not consider their purpose of life and their fertility concerns. Many studies reported most cancer patients had severe depressive symptoms and PTSD symptoms for several months from the cancer diagnosis (e.g., Vin-Raviv, 2013).

Many studies of these systematic review reported that semi-structured psycho-educational therapy decreased psychological distress in early stage of cancer (e.g., Fawzy, 1994). Psycho-educational therapy means one of psychotherapies focused on the improvement of stress coping strategies, interpersonal communication and relationships.

The patient's experience of cancer could be a crucial influence on partners' emotional life and well-being. In general, many partners take an active role in key decisions concerning treatment options and provide emotional and instrumental support to the patient. The meta-analysis study indicated that there is a moderate correlation between distress in persons with cancer and their partners' distress (Hagedoorn, 2008).

Couple therapy, however, is effective for cancer patients and spouses in order to improve their mental illness and marital communications. Depressive symptoms with both cancer patients and their partners were decreased by the couple therapies (Manne, 2005; McLean, 2007).

Thus, we conducted to make the effective psychological therapy for cancer patients in fertility preservation settings: The Oncofertility! Psycho-Education And Couple Enrichment (O!PEACE) therapy (Koizumi, 2014; 2015).

The O!PEACE therapy is a short-term approach based on solution-focused therapy and couple & family therapy. It consists of two sessions. It takes about 70 minutes per a session.

The contents of the in-depth manual of the O!PEACE therapy (Figure 1) is follows;

1. Psycho-education of oncofertility
2. Supportive therapy of life and fertility crisis
3. Solution-focused approach to distress of cancer and fertility
4. Relaxation skill training
5. Assertive communication between couple

We calculated the inter-rater agreement of O!PEACE therapy using Kappa coefficient. The results are as follows;

K= .778- .949 for each psychologists
K= .856 for all contents of the therapy

Declare of conflict

The authors have no conflict of interest to disclose with respect to this presentation.

Figure 1: The manual of the O!PEACE therapy

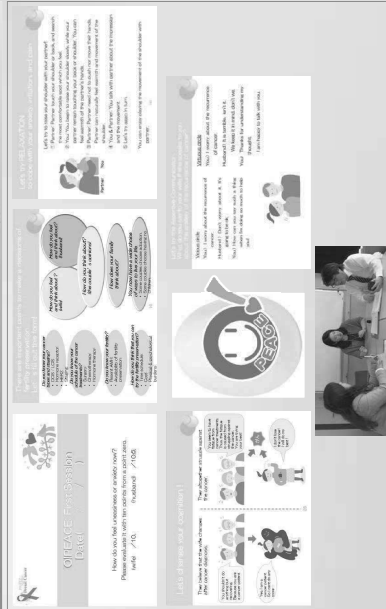
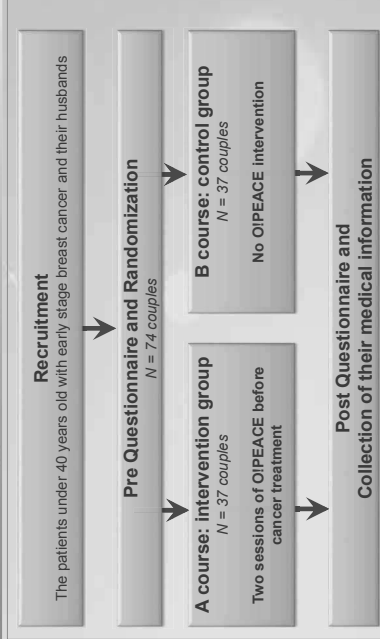


Figure 2: RCT study protocol



Results and Discussions: the progress report

We have investigated since June 1st 2015. Thirty-seven couples participated in this trial. Of 37, we can analyze 24 couples' questionnaire data. Rest 13 are now in the survey period. We tried to conduct ANCOVA with repeated measures as a test. Their psychopathology and having children are recognized as the covariates.

Husbands' HADS score was significantly improved by O!PEACE ($F(1,22)=2.964$, $p<.10$) (Figure 3). Wives's QOL score was also significantly improved by O!PEACE ($F(1,20)=5.739$, $p<.05$) (Figure 4).

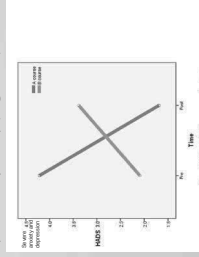


Figure 3. Husbands' HADS score among couples with breast cancer

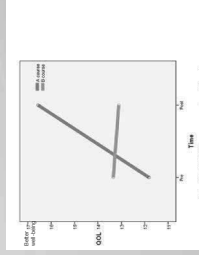


Figure 4. Wives' QOL score among couples with breast cancer

These pilot analyses shows that both husbands and wives who receive O!PEACE get better than the couples who are in the control group significantly.

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This work was supported by Health Labour Sciences Research Grant #H26-Cancer-017 (The Ministry of Health Labour and Welfare).

Purpose

The aim of this study is to examine whether the psychotherapy "O!PEACE" can reduce concerns of fertility and psychological distress, and improve marital communication with cancer patients and their partners.

Method

We conduct the randomized controlled trials for early stage breast cancer patients and their partners. Top eight hospitals in Japan conduct this study.

Subjects: In advance, we calculated the power analysis of the sample size. Total 74 women who are just diagnosed the early stage breast cancer and their husbands will participate in this study.

Protocol (Figure 2): The couples will be randomized into two groups: either the intervention group (two sessions of the O!PEACE therapy intervention) or the control group (no psychological intervention). The couples participate in either groups, and they all fill out pre-post questionnaires. We must complete these procedure before they begin to receive some cancer treatment.

Intervention: O!PEACE therapy. The intervention group must participate in all sessions by couples before.

Main Outcome Measures: The international standard scales of mental health, resilience, and marital relationships.