



Research paper

China's cancer patients' perceptions, attitudes and participation in clinical trials of complementary and alternative medicine: A multi-center cross-sectional study

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ABSTRACT

Introduction: Complementary and alternative medicine is quite popular among oncologists and cancer patients, nevertheless many clinical trials of complementary and alternative medicine (CTCAM) are not registered. This study was designed to investigate the perceptions of cancer patients toward CTCAM in China and their attitudes to participating in such trials.

Methods: A multicenter cross-sectional study was conducted from June to December 2016. Cancer inpatients over the age of 18 years and with a clear disease diagnosis were recruited from the integrative oncology departments of five general hospitals in Shanghai, China. After obtaining informed consent and having had the definitions of CTCAM, CAM and CT explained by their oncologist, each participant completed a questionnaire in a face to face interviews under the guidance of the oncologist.

Results: A total of 662 cancer patients participated in this study. Half (49.8%) self-reported they understood the meaning of clinical trials (CTs), 14 cancer patients (2.1%) had participated in CTs before, but none had participated in CTCAM. Of cancer patients who knew about CTs, most showed conditional attitude towards participating in CTCAM. To participate in CTCAM, most wanted to get better treatment (78.8%). Potential risks during the trials (55.8%) and patients' unwillingness to be treated as test subjects (37.3%) were the main reasons why the patients refused to participate. Their main issues were about the purpose and effects of the treatment (90.3%), their privacy (81.8%), and potential risks and adverse effects (81.8%). Predictive factors associated with "cancer patients knowing about CTs" included age (≤ 59 years, $P = 0.006$), ECOG-PS score (≤ 2 , $P < 0.001$) and education background (college/university, $P < 0.001$).

Conclusions: In China, cancer patients do not appear to have a good knowledge of understanding about taking part in CTs. However, many cancer patients showed great interest in participating in CTCAM.

1. Introduction

Cancer statistics estimated that 4,292,000 new cancer cases and 2,814,000 deaths occurred in China in 2015 [1]. For anti-cancer treatment, complementary and alternative medicine (CAM) is quite popular among oncologists and cancer patients [2–7]. In China, there is no doubt that traditional Chinese medicine has the dominant position among all the CAM therapies [8]. Clinical trial (CT), is any investigation in human subjects to study the effects of new drugs or medical devices, is a hit nowadays [9–12]. However, many problems still exist in CTs, such as the unproven benefits, potential risks, ethical issues, etc. Furthermore, the perceptions and attitudes of the cancer patients toward CTs are multifarious, which could influence their decisions to

participate in CTs [13–17]. Clinical trials of complementary and alternative medicine (CTCAM) are also important, though many CTCAM are not registered [7,18]. A study of randomized controlled trials (RCT) of CAM oncology, only 59 RCTs have been published by the top five journals in general and internal medicine, clinical oncology, and CAM from 2006 to 2015 [18] and the number of citations of these RCTs is low. The purpose of this study was to explore the perceptions and attitudes of Chinese cancer patients toward CTCAM. The hypothesis of this study was that only a few cancer patients would know about CTs and that their participation rate in a CT would be low.

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2. Methods

2.1. Study design

Through a systematic review of the literature and discussion with experienced medical oncologists and CAM physicians, a multicenter cross-sectional study was designed. The method of selecting participants was census. The participants included in this study were cancer inpatients from department of integrative oncology of five general hospitals (namely Changhai Hospital, Changzheng Hospital, Longhua Hospital, Shuguang Hospital and Yueyang Hospital) in Shanghai, China from June to December 2016. Each participant was required to fill out a questionnaire. This study was approved by Ethics Committee of Integrative Medicine Institution, Changhai Hospital, Second Military Medical University.

2.2. Inclusion and exclusion criteria

The inclusion criteria were: (1) age ≥ 18 years old; (2) with clear disease diagnosis; (3) speaking Chinese. The exclusion criteria were: (1) patients do not know they have cancer; (2) patients or family members refuse to participate; (3) with language communication barrier.

2.3. Questionnaire

Before filling out the questionnaire, the oncologists would explain the definitions of CAM, CT and CTCAM to the participants, then examples would be given so that they could have better understanding of these three terms. For this study, CAM was defined as therapies such as Chinese herbal medicine/Chinese patent medicine, acupuncture, Tai Chi, Massage, Qigong, Yoga, diet therapy, etc [2,7]. The questionnaire was divided into three sections. Section one covered the baseline information about the cancer patients: age, gender, education background, type of cancer, disease duration, clinical stage, Eastern Co-operation Oncology Group-performance status (ECOG-PS) score, treatment(s) the cancer patients experienced before the survey, health insurance, and annual household income. Then the patients would be asked two questions: 1) do you know about CT? If the cancer patients answered “No”, the questionnaire will be completed at this point. Instead, if they chose “Yes”, they would be asked to fill out the rest sections. 2) whether you have participated in CTs? If they answered “Yes”, then gave the detail intervention. Section two mainly dealt with the attitudes and the willingness of the cancer patients to participate in CTCAM by using a Likert scale (see Fig. 1). There were nine questions in section two, such as “whether the cancer patients would like to participate in CTCAM when Western medicine has (does not have) explicit therapeutic regimen”, “whether the oncologists would tell the cancer patients all the benefits, potential risks, and protection of rights and interests of CTCAM”, and “whether the cancer patients would be afraid of being deceived when participating in CTCAM”. The last section included the perceptions and practice of the cancer patients toward CTCAM. Questions in this section mainly concerned about “why the cancer patients would (not) take part in CTCAM”, “the purpose and benefits of participating in CTCAM”, “what rights and interests should be protected”, and “what kind of CTCAM cancer patients might be interested in”.

2.4. Data collection

Questionnaire data was collected in face to face interviews and under the guidance of oncologists (Dr. Yifu Fan, Dr. Cheng Wu, and Dr. Yuyu Guo). The baseline information was obtained from the electronic database of hospitalized medical records.

2.5. Sample size

In advance of the main study, a pilot study was conducted to estimate the knowledge about CTs in 50 Chinese cancer patients from Changhai Hospital, Shanghai, China in order to provide data for a power calculation for this study. There were 20 (40%) cancer patients self-reported having knowledge about CTs. Therefore, the sample size of this study was 461 and was calculated according to the results of the pilot study with a 95% confidence interval and a 5% margin of error. A drop-out rate of 20% was also considered.

2.6. Statistical analysis

Frequency distribution and mean \pm standard deviation (SD) were used to summarize the cancer patients' baseline information. The difference between the two groups of cancer patients (“know about CTs” and “did not know about CTs”) were assessed by two independent samples *t*-test, chi-square test (Fisher-test was also used if required) and Mann-Whitney *U* test. For further analysis, univariate and multivariate analyses were used. Multivariate analysis began with all variables having *P*-values < 0.25 from the univariate analysis such as ECOG-PS score, education background, clinical stage, and annual household income. Age and sex were kept regardless of their significance. All the difference was considered to be significant when $P < 0.05$ and all the *P*-values were two tailed. All the data were processed by SPSS version 21.0 (SPSS Inc., Chicago, IL, USA).

3. Results

A total of 1002 questionnaires were sent to the cancer patients and 752 were returned (250 patients were excluded according to the

Table 1
Characteristics of the cancer patients ($N = 662$).

Variable	Know about CT ($n = 330$)	Unknow about CT ($n = 332$)	<i>P</i> -value
Age (years)	59.0 \pm 11.3	63.2 \pm 11.1	< 0.001
Sex, <i>n</i> (%)			0.758
Male	169 (51.2)	174 (52.4)	
Female	161 (48.8)	158 (47.6)	
Education background			< 0.001
Primary school	48 (14.6)	85 (25.6)	
High school	179 (54.2)	192 (57.8)	
College or university	103 (31.2)	55 (16.6)	
Annual household income			0.059
$< \$12,000$	77 (23.3)	113 (34.0)	
$\$12,000$ – $\$18,000$	130 (39.4)	116 (35.0)	
$\$18,000$ – $\$30,000$	67 (20.3)	61 (18.4)	
$\$30,000$ – $\$45,000$	33 (10.0)	27 (8.1)	
$\$45,000$ – $\$150,000$	19 (5.8)	11 (3.3)	
$> \$150,000$	4 (1.2)	4 (1.2)	
Health insurance			0.463
National medical card	101 (30.6)	93 (28.0)	
Non-national medical card	229 (69.4)	239 (72.0)	
Disease duration (month)	29.6 \pm 32.2	27.8 \pm 30.3	0.477
Clinical stage			0.042
Stage I	101 (30.6)	79 (23.8)	
Stage II	69 (20.9)	69 (20.8)	
Stage III	75 (22.7)	67 (20.2)	
Stage IV	85 (25.8)	117 (35.2)	
ECOG-PS score			< 0.001
0	23 (7.0)	19 (5.7)	
1	274 (83.0)	223 (67.2)	
2	26 (7.9)	62 (18.7)	
3	6 (1.8)	24 (7.2)	
4	1 (0.3)	4 (1.2)	

CT: clinical trial; ECOG-PS: Eastern Cooperative Oncology Group-performance status.

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