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• Methodology

Standards of Reporting Kampo Products (STORK) in research articles

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ABSTRACT

There had been no standardized rules for citing ethical Kampo products used in clinical trials in journal articles. Although the name of a Kampo manufacturer was described in 77.9% of research articles, the name and ratios of crude drug components of Kampo formulas were not described in 77.5% of these papers. Considering the importance of proper characterization of interventions in the Consolidated Standards of Reporting Trials (CONSORT) checklist, we hereby propose the use of the Standards of Reporting Kampo Products (STORK) website, http://mpdb.nibiohn.go.jp/stork, as a reference for Kampo products. This will provide an official source on the internet for verified information on individual Kampo formulations for citation purposes in clinical research articles.

Keywords: medicine, Kampo; Evidence Reports on Kampo Treatment; randomized controlled trial; Consolidated Standards of Reporting Trials (CONSORT); Standards of Reporting Kampo Products (STORK)

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1 Introduction

Kampo medicines for ethical use have been prescribed within the framework of the National Health Insurance system in Japan. Kampo medicine, combined with Western medicine, are forming a highly advanced unified system of integrative medicine.[1–3] Randomized controlled trials (RCTs) have been performed to provide clinical evidence for Kampo medicines. The Special Committee for Evidence-Based Medicine (EBM) of the Japan Society for Oriental Medicine (JSOM) has compiled structured abstracts (SAs) of RCTs on Kampo medicines since 2005, and has published the SAs as Evidence Reports on Kampo Treatment (EKAT) since 2007.[4] An English version is available (http://www.jsom.or.jp/medical/ebm/index.html). The proper means of describing Kampo formulas has been unclear in the reporting of RCTs. For example, some authors cited classical literature, while others showed figures from three-dimensional high-performance liquid chromatography to characterize the formula.[5] An analysis of EKAT revealed that the names of Kampo manufacturers were described in 79.1% of RCTs, while

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for crude drug components of Kampo formulations, neither their names nor their component ratios were reported in 77.5% of RCTs (Table 1).

This might reflect differences among the "Instructions for Authors" in different journals. Kampo products in Japan are manufactured by Kampo medicine manufacturers, all of which are members of the Japan Kampo Medicines Manufactures Association (JKMA; http://www.nikkankyo.org/), under the regulation of the *Act on Securing Quality*, *Efficacy and Safety of Pharmaceuticals*, *Medical Devices*, *Regenerative and Cellular Therapy Products*, *Gene Therapy Products*, and *Cosmetics*, including the *Japanese Pharmacopeia* (JP) and relevant notifications such as *Good Manufacturing Practice*. Therefore, for Japanese readers of the articles of RCTs in which Kampo products are used, identification of the Kampo product is easy. However, for international readers, correct identification of each Kampo product is not easy, because access to the relevant information is limited.

2 The Consolidated Standards of Reporting Trials

The Consolidated Standards of Reporting Trials (CONSORT) is a checklist for fully reporting RCTs, and ensuring they conform to universally recognized formats. The first edition was developed in 1996, and was revised in 2002 and 2010. The latest version is the CONSORT 2010 Statement.[6] The CONSORT Statement is "an evidence-based, minimum set of recommendations for reporting RCTs. It offers a standard way for authors to prepare reports of trial findings, facilitating their complete and transparent reporting, and aiding their critical appraisal and interpretation" (http://www.consort-statement.org/).[6] The CONSORT 2010 Statement comprises a 25-item checklist and a flow diagram. Notably, for drug "interventions" information would include the drug name, dose, method of administration (such as oral and intravenous), timing and duration of administration, conditions under which interventions are done and titration regimen if applicable (http://www.consort-statement.org/checklists/view/32-consort/78-interventions).

3 Standards of Reporting Kampo Products

Standards of Reporting Kampo Products (STORK), as a reference for Kampo extracted products, was developed to provide simple and complete documents that can be cited by anyone to show the formulas of Kampo medicines used in studies.

The name of the website was originally KCONSORT, which stood for Kampo-CONSORT. The purpose of this project was to increase awareness of the CONSORT statement in Japan, especially in the area of traditional medicine. However, as CONSORT became fairly well known in Japan, and this project was not officially part of the CONSORT Group, we decided to change the name.

STORK was developed as KCONSORT in 2009, and was renamed STORK in December 2016. The STORK website (http://mpdb.nibiohn.go.jp/stork) provides information on the characteristics of 148 ethical Kampo products marketed in Japan. This corresponds to Item 5 (Intervention) of the CONSORT 2010 Statement. STORK does not provide information on quality control of Kampo products used in RCTs. It shows information on the specification standards and the proportion of components of each Kampo product, by linking to official standards. Among the 148 Kampo formulas in STORK, there are 27 formulas from the JP XVII, and 121 formulas that are

Table 1 Citation analysis of Kampo formulations used in RCTs of interventions

Items	Number of RCTs	Percentage (%)
Name of Kampo manufacturer		
Yes	299	79.1
Yes but only in part	3	0.8
No	76	20.1
Name & component ratio of crude drug component of Kampo formulation		
Yes	64	16.9
Yes but only name of crude drug	20	5.3
Yes but cited from another article	1	0.3
Neither of the above	293	77.5
Dosage of Kampo formulations		
Yes	353	93.4
No	25	6.6

RCT: randomized controlled trial.