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Clinical trials in allied medical fields: A cross-sectional analysis of World Health Organization International Clinical Trial Registry Platform

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ABSTRACT

Background: Clinical trials are mandatory for evidence-based practice. Hardly, any data are available regarding the number of clinical trials and their methodological quality that are conducted in allied fields of medicine.

Objective: The present study was envisaged to assess methodological quality of trials in allied medical fields.

Materials and Methods: Registered clinical trials in World Health Organization International Clinical Trials Registry Platform (<http://apps.who.int/trialsearch/AdvSearch.aspx>) in the following fields were extracted: Acupuncture; Ayurveda; biofeedback; complementary and alternate medicine; herbal; homeopathy; massage; naturopathy; Reiki; Siddha; Unani; and yoga. The eligible studies were assessed for the following key details: Type of sponsors; health condition in which the trial has been conducted; recruitment status; study design; if randomization was present, method of randomization and allocation concealment; single or multi-centric; retrospective or prospective registration; and publication status in case of completed studies.

Results: A total of 276 clinical trials were registered majority of which have been proposed to be conducted in the field of oncology and psychiatry. Most of the clinical trials were done in single centers (87.75%), and almost all the clinical trials were investigator-initiated with pharmaceutical company sponsored studies contributing to a maximum extent of 24.5%. A large majority of the study designs were interventional where almost 85% of the studies were randomized controlled trials. However, an appropriate method of randomization was mentioned only in 27.4%, and the rate of allocation concealment was found to be just 5.5%. Only 1–2% of the completed studies were published, and the average rate of retrospective registration was found to be 23.6% in various fields.

Conclusion: The number of clinical trials done in allied fields of medicine other than the allopathic system has lowered down, and furthermore focus is required regarding the methodological quality of these trials and more support from various organizations.

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1. Introduction

Clinical trials generate high-quality evidence that may then get incorporated into national/international guidelines and meta-analysis, finally culminating in an evidence-based practice (EBP)

[1]. For EBP, clinical trials have to be conducted with robust methodology and published to allow more transparency of the findings. In this era of shared decision-making, even patients should have access for such clinical trials, and this is the very purpose of creating clinical trials registry platform. There exist several regional clinical trial registries serving different regions of the world and the World Health Organization International Clinical Trial Registry Platform (WHO-ICTRP) initiated in 2006 serves as a portal of access to these registries [2].

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Studies of clinical trial registries in some of the portfolios in allopathic medicine revealed crucial findings [3,4] which include poor quality of publication of clinical trials in complementary and alternate systems of medicine [5] and dentistry [6] and also paucity of available data regarding the clinical trial methodology in these fields. In addition, there is no data on clinical trials conducted or published in other allied fields of medicine such as acupuncture, Ayurveda, homeopathy, massage, naturopathy, Reiki, Siddha, Unani, and yoga. Hence, the present study was envisaged with an objective to obtain a holistic view of methodological quality and trends of clinical trials done in all these fields.

2. Materials and methods

The study was conducted between September 2014 and January 2015. Following keywords were used for the search in WHO-ICTRP (<http://apps.who.int/trialsearch/AdvSearch.aspx>): Acupuncture; Ayurveda; biofeedback; complementary and alternate medicine (CAM); herbal; homeopathy; massage; naturopathy; Reiki; Siddha; Unani; and yoga. Individually, the above-mentioned keywords were used in the “Intervention” section without any limits in either the recruiting status or date of registration fields. Both authors independently retrieved the studies from the trial registry emerging from search results, and duplicate studies were removed from the final analysis.

Each of the registered studies was assessed for the following details: Source of primary registry (Clinical Trial Registry of India [CTRI], Chinese Clinical Trial Registry [ChiCTR], Korean Clinical Trial Registry [KCT], clinicaltrials.gov [CTG], German Clinical Trials Register [GermanCTR]; International Standards of Reporting Clinical Trials [ISRCTN], Netherland’s Trial Register [NTR], European Clinical Trial Database [EudRACT], Brazilian Clinical Trial Registry [REBEC], Iranian Registry of Clinical Trials [IRCT], Hong Kong Clinical Trial Register, Australia and New Zealand Trial Register, Japan Clinical Trial Registry [UMIN-CTR]); type of sponsors (academic or commercial); health condition in which the trial has been conducted; year of registration; Institutional Ethics Committee (IEC) approval obtained or not; recruitment status (ongoing/completed); study design (observational/interventional [nonrandomized/randomized (open label, single blind, and double blind)]); if randomization was done, method of randomization (computer generated [CG], random number table [RNT]) and allocation concealment; phase of clinical trials (I, II, III, and IV); single or multicentric; type of study participants (patients/healthy volunteers); retrospective or prospective registration; and publication status in case of completed studies.

3. Results

3.1. Number of clinical trials

The search strategy revealed a total of 342 studies (acupuncture – 3; Ayurveda – 11; biofeedback – 27; CAM – 9; herbal – 53; homeopathy – 31; massage – 51; naturopathy – 15; Reiki – 9; Siddha – 7; Unani – 7; and yoga – 119). Of the studies retrieved under CAM ($n = 9$), one was proposed to evaluate Ayurveda, two studies retrieved under massage and one with naturopathy were proposed to evaluate acupuncture and after removing the duplicates and inappropriate studies, a total of 276 studies were included in the final analysis (acupuncture – 6; Ayurveda – 10; biofeedback – 25; CAM – 8; herbal – 53; homeopathy – 21; massage – 38; Reiki – 1; Siddha – 5; Unani – 2; and yoga – 107). A summary of various characteristics and methodological quality of various clinical trials is depicted in Table 1.

3.2. Characteristics of clinical trials

3.2.1. Acupuncture

A total of six studies were retrieved (3 – ChiCTR; CTG – 2 [one each in the United States (US) and United Kingdom (UK)] and one from KCT). All these studies were investigator-initiated (one each in the years 2005, 2008, 2010, and 2011 and two in 2012) and only four studies had mentioned that they had obtained IEC approval. Regarding the health condition in which the clinical trials are carried out in Acupuncture, one each was in ophthalmology (juvenile myopia), psychiatry (attention deficit hyperactivity disorder [ADHD]), cardiovascular system (chronic stable angina) and oncology (breast and head and neck cancer) and two were in the field of central nervous system disorders (cerebral palsy and spastic paralysis). All the studies were being done in a single center in patients, and only one study had been completed.

3.2.2. Ayurveda

There were a total of 10 studies (seven in CTG [US – 5; one each in Singapore and France], two in CTRI and one in GermanCTR) pertaining to this field. All these studies were from academia (three each in 2006 and 2007, two in 2012 and one each in 2009 and 2011). Regarding the health conditions where the studies are being carried out, seven were in the field of oncology (three in breast cancer, two in all types of cancer patients and one each in prostate cancer and chronic myeloid leukemia [CML]) and one each in mental retardation and lifestyle. Furthermore, 9 of the 10 studies are conducted in patients and one in healthy volunteers, seven are being carried out in a single center and three are multi-centric and only one was completed.

3.2.3. Biofeedback

A total of 24 studies were retrieved (15 – CTG [14 – US, 1 – Taiwan], 3 – GermanCTR, two each from ISRCTN [both from UK] and NTR, and 1 from ChiCTR) of which only 2/24 (8.3%) was from commercial sponsors. A total of five studies were conducted each in the field of psychiatry (one each in ADHD and alcohol de addiction, anxiety, cognitive behavioral therapy and psychotherapy) and urinary incontinence, three each in the disorders of central nervous system (two in cerebral palsy and one in migraine) and anal incontinence, two with lower limb disorders (one each with quadriceps inhibition and drop foot) and one each in insomnia, pelvic floor disorder, erectile dysfunction, cancer, diabetes mellitus, and neuropathic pain. Only 9/24 (37.5%) studies had mentioned about having obtained IEC approval, and a majority (23/24, 95.8%) were done in a single center. In addition, only one study was completed, and 23/24 (95.8%) studies were carried out in patients while only one in a healthy volunteer.

3.2.4. Complementary and alternate medicine

A total of eight clinical trials (6 – CTG [5 – US and 1 – Mexico], one each from CTRI and ISRCTN [Chile]) were registered. All the eight studies were from academia, and only three had mentioned about IEC approval. Half of the studies were being carried out in oncology (one each in CML, breast cancer, prostate cancer, and ovarian cancer), two in human immunodeficiency virus-infected patients and one each in ulcerative colitis and elderly population. Five out of eight studies were completed; two are ongoing, and one was terminated. All the studies were being carried out in a single center in patients.

3.2.5. Herbal

Fifty-three clinical trials (19 each from CTG and CTRI; 9 – ChiCTR; 3 – IRCT; 2 – UMIN-CTR and one from ISRCTN) have been registered of which 40 (75.5%) were from academics and 13 (24.5%)

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