Chapter 2
Integrative Medicine and Prospective Research on CAM

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ABSTRACT

There is a link between integrative medicine (IM) and prospective research on complementary and alternative medicine (CAM). IM is the future direction of CAM and research is needed to support clinical practice. Meaning of IM, proposed models of IM, and existing research on IM will be presented. Prospective research on CAM will cover methodologies presenting randomised controlled trials, harms studies of CAM in kidney disease, and a gap of CAM research. Study design and outcome measures are current challenges in CAM/IM research. Several networks of CAM research worldwide are still working on them and have proposed possible alternative approaches, such as pragmatic clinical trials and cohort multiple randomised controlled trials. These approaches would solve some limitations of randomised controlled trials in CAM research.

INTRODUCTION

The World Health Organization (WHO) Traditional Medicine Strategy 2014-2023 suggested promoting universal health coverage by integrating CAM into conventional medicine (World Health Organization, 2013). Three Asian countries provide full coverage of traditional medicine integrated into their national health system, i.e. China, South Korea and Vietnam. In Switzerland, partial integration of CAM is employed (World Health Organization, 2013). Integrative medicine (IM) is a new term in the CAM field, compared with the terms complementary or alternative medicine. There is no consensus on the definition of IM. One definition of this term focused on its meaning is 'IM is the use of CAM integrated into conventional medicine, which should be supported by evidence' (Walach, 2010). Hu et al. (2015) proposed five key elements of IM as described by an expert consensus: (1) presence of aspects of both CAM and conventional medicine; (2) goals of health and healing; (3) holistic approach; (4) optimum treatment; and (5) uses the body's innate healing response.

Patients with chronic diseases tend to use CAM with their conventional medicine as they hope that CAM could complement it, including patients with kidney disease (Tangkiatkumjai et al., 2014). Several chronic diseases are frequently treated by IM, such as asthma, rheumatic disease, chronic inflammatory bowel disorder, and chronic pain (Dobos & Tao, 2011). Patients need to know how to integrate CAM with their conventional medicine in order to obtain both higher efficacy and lower adverse effects of conventional medicine. Both CAM and conventional systems have their own advantages and disadvantages, so their integration would be an option for some illnesses that cannot be fully treated by one system. CAM users and conventional practitioners are also concerned about the interaction between them, which may be either synergistic or antagonistic. Research on IM is therefore required to support clinical decision-making. This chapter will describe existing IM models, research on IM and a checklist for reporting research on IM. The section of prospective research on CAM methodologies will: (1) discuss a research approach to building up evidence for CAM; (2) highlight major issues of methodologies of randomised controlled trials (RCTs) in CAM/IM research; (3) propose plausible solutions for those issues; and (4) provide prospective research on CAM/IM in kidney diseases.

Some models of an IM service have been proposed in primary care in many countries, which includes 1) the choice between systematic or individual IM; and 2) the need for collaboration between CAM and conventional practitioners (Templeman & Robinson, 2011). Such IM models would give an idea for practitioners who would like to develop an IM service in their setting. However, outcome studies of IM services are very limited. Khorsan et al. (2011) and Grant et al. (2015) systematically reviewed IM research and faced a challenge of inconsistently defined IM, which was an obstacle to analyzing the findings. To promote robust reporting evidence on IM, Hu et al. (2015) proposed a checklist for standard reporting clinical trials of IM. Regarding CAM research, Fønnebø et al. (2007) proposed 'Reverse research strategies' between conventional and alternative medicine, which seems to be suitable for CAM/IM research. CAM research should start with what people use in practice, followed by the safety and efficacy of CAM, and pre-clinical studies. This strategy reverses research on conventional medicine, which starts with *in vitro* and *in vivo*, followed by phase I clinical trials to test its safety, then RCTs to prove its efficacy. For example, in the case of herbal medicine, its safety should be investigated prior to its effectiveness and mechanism of action. If positive and negative effects of herbal medicine were examined in the same way as conventional medicine, it would be costly and time consuming. Further studies are required to provide robust evidence for the efficacy and safety of CAM. This chapter focuses on the methodology of RCTs. As the methodology of choice, RCTs have been criticised by CAM researchers because they are inappropriate for CAM. Fischer et al. (2012) systematically reviewed several RCTs of CAM methods and effectiveness, and found five key issues of methodological problems: (1) double-blinding; (2) randomisation; (3) standardised CAM modalities; (4) defined outcomes in CAM; and (5) a choice of a proper control group. They have also suggested pragmatic clinical trials (PCTs) for CAM research, rather than RCTs, as an appropriate methodology for CAM research, and solutions for such issues that will be described later. However, Relton (2013) disagreed that PCTs were suitable for CAM research as these trials may increase some biases, such as cognitive measurement and selection biases. She proposed a new approach for CAM research: 'cohort multiple randomised controlled trial' design (cmRCT). This method is promising to solving unsuccessful recruitment, randomisation and blinding in CAM research. In addition, a mixed methods study is another approach for CAM research. The qualitative method alongside a clinical trial will better understand the effects of interventions and how they are experienced by patients (Lewin et al., 2009).

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