The Case for Case History Research by Maureen Robertson MSc M.NIMH and Keith Robertson MSc (Herb Med) F.NIMH

Introduction

This paper represents the culmination of seventeen years of enquiry into identifying suitable methods which are holistic, cruelty free and which honour our tradition of whole plant preparations and so produce information which is relevant to herbal practitioners. Patient-practitioner centred and phenomenological methods are put forward as being the most appropriate considering the nature of holistic practice as well as the financial and time constraints for individual practitioners and within the profession.

Current Herbal Research

We are starting to witness a paradigm shift where interest is growing towards conducting research which embraces the precepts of holistic medicine (St George, 2001). As commented on elsewhere in this volume (cf Caldock page…), it is important to recognise the distinction between herbal medicine – a holistic, practitioner led discipline and herbal medication – an over the counter product that can often bear slim resemblance to the original plant (Barker, 2007).

The 'gold standard' of randomised, controlled, double blinded placebo trials (RCT's) are based on the model of viewing herbs as pharmacological agents only and removing the practitioner/observer from the therapeutic effect thus producing quantifiable and statistically significant data but for herbal medication alone. The synergistic interactions of constituents within a herb itself as well as combined within a prescription and the importance of the therapeutic relationship between patient-practitioner and plant as experienced in herbal practice are not considered in this type of trial.

This is not to say that herbalists are unable to conduct RCT's but only if the experience of the patient on the trial mirrors that of an individual consultation can such trials inform herbal practice. Examples are the treatment of menopausal symptoms by qualified herbal practitioners (Green, *et al*. 2007) and into herbal relief of chronic pain (Mills *et al.*1996). This so called 'black box' approach to RCT's (St George, 2001) is a more realistic framework to represent what actually goes on in herbal practice.

Therefore, the majority of herbal research available in the literature is limited in terms of informing professional herbal practice. This is for a variety of reasons:

1. Most research is conducted by non herbal practitioners using extracts which have been manipulated from whole plant extracts (allowing patenting) or using isolated constituents and are therefore not in the same whole spectrum plant format as are used in professional practice (Lecrubier *et al.*, 2002).

2. Many lab based projects use isolated constituents of a herb, thereby removing a plethora of other unknown constituents which can have crucially important roles such as increasing bioavailability/assimilation or tempering potential toxic constituents (Weiss, 1988)

3. Focusing primarily on herbs as pharmacological agents does not consider energetic, synergistic and traditional uses of herbs as is the case in all traditional systems of herbal medicine such as Ayurveda, Traditional Chinese Medicine and Humoral medicine (Wood, 2004).

4. Adopting the same preparation, same dose, same duration of treatment approach in non herbalist led clinical trials does not concur with the individual tailor-made treatment plan and variable prescribing witnessed in professional herbal practice. Taking an individual's unique life story into account and how they progress with the treatment necessitates flexibility within herbal treatment, allowing adjustments in lifestyle and dietary changes as well as the herbal prescription itself to take place as required. This flexibility as well as the effects of the therapeutic relationship itself, where a patient works with the same practitioner, provides a very different picture to that portrayed within standard clinical trials. For example, the trial undertaken by Bensoussan *et al.* (1998), compared individualised treatment to standard formula treatment and found that the individualised treatment maintained longer lasting positive effects for patients after they had discontinued the treatment than the non individualised treatment.

Likewise, one herb for all individuals with a similar condition does not take into account constitutional or temperament types of a patient to make the herbal treatment more specific to achieve a greater therapeutic impact (Lad & Frawley, 2002 and Tobyn, 1997).

5. Sometimes the wrong species and part of plant are used as well as applying the herb to non-traditional therapeutic use (Taylor, *et al.*, 2003).

The Future of Appropriate Research Initiatives for Herbal Medicine

Given the preceding arguments, it is clear to us that we have not inherited a research paradigm and relevant methodologies immediately applicable without qualifying our specific needs as a profession. Large scale clinical trials, if conducted sensibly would, of course, be a possible route. However, the author's main research initiatives have been through their association with the Scottish School of Herbal Medicine and as a small educational charity, it does not have the financial resources to undertake this type of research. We have, therefore, over the years been exploring new methodologies and testing their appropriateness to herbal practice.

The main research initiatives that we have explored so far are: Goethean Science and also Case Studies. Goethean, or as we have termed it, Contemplative Science is certainly pushing the boundaries of the scientific method in attempting to encompass both subjective and objective considerations (Robertson, 2003, Robertson & Robertson 2006 and Robertson, 2009). As such, it is a bold enterprise. However, according to Kaptchuk (1998), practices such as blinding and randomisation only became parts of orthodox medical research after they were first applied to unorthodox practices, such as homoeopathy and psychic healing. In this we feel we are on the cutting edge of herbal medicine research. To quote Lewith *et.al* (2003) p 24:

> "A creative tension between the established and the frontier can advance scientific knowledge and help us understand both the benefits and limitations of the scientific process for medicine."

The author's have also become interested in the case study and by extension the case series as a further appropriate method. This has been developed through a number of MSc dissertations (Wood, 2005), (Wolfe, 2008) and Duxbury, (2008). One of the main criticisms against using individual case studies is how you can make generalisations from one study. However, according to Yin (2003) p 10,

> "…case studies, like experiments are generalisable to theoretical propositions and not to populations or universes."

So we are looking at analytical rather than statistical generalisation. Another criticism is that they are purely qualitative in nature, however, Yin 2003 again states p14:

> "…case studies can include and even be limited to quantitative evidence."

Importantly, Yin 2003 p15 also states that in evaluation research, case studies can:

> "…explain the presumed causal links in real life interventions that are too complex for the survey or experimental strategies."

Also, Lukoff et al., 1998 p44 in a comprehensive overview reasons:

> "because case studies examine people in or close to real situations, and because they do not distort naturally occurring behavior through experimental manipulation and the setting up of artificial conditions, they usually offer better external validity than do controlled experiments."

We are grateful to the input from the University of Wales via our research advisor, Iris Musa for suggesting we look at single subject experimental design studies or n=1. Case history research in general, has so far been the domain of the social sciences and while they are widely used in the fields of business, education and governmental research, they have generally been neglected as a clinical research method until recently (Thompson, 2004). Having looked into n=1 studies, whilst fitting the requirement for personalised treatment, the protocol as used in orthodox medicine may not necessarily fit. The design requires switching on and off the treatment and therefore, interventions studied should have a relatively short duration of action with rapid onset of effect and an equally rapid reversal of effect when treatment stops. In herbal medicine, effects can be slow and long lasting and it would be difficult to switch off holistic advice aimed at lifestyle changes etc. (Hart & Sutton, 2003). However, the approach is entering the literature with attempts to test the efficacy of herbs using this design (Coxeter et al. 2003) with varying results. In addressing the question of generalisability, Janosky, (2005) suggests either choosing a case that is typical (for herbalists this could be a common condition or constitutional type disorder) or by conducting replication studies involving variation in researchers, subjects, or practices. This would certainly be applicable to herbal practice.

Whilst n-of-1 studies may not be most appropriate methodology in the authors' opinion, the widespread interest being shown them in the literature, is certainly putting the case study further up the research agenda. What they do introduce to the fabric of design is the suggestion that at least one quantitative measure is introduced into each study eg blood pressure, cholesterol levels etc. With a particular reference to CAM research, Thompson (2004), (a previous SSHM tutor), in looking at the future of research design into homeopathic trials, has suggested the use of the "Formal Case Study" (FCS) and he proposes that the trustworthiness of conclusions can be ensured by qualitative research concepts such as triangulation, groundedness, respondent validation and reflexivity.

Conclusion

This is a rich seam which deserves our attention. The author's future research strategy, therefore, is to develop a case study database of herbal interventions, which can be used to strengthen the design of such studies and advance herbal knowledge. Herbal practitioners have an extremely precious resource hidden in their individual case histories which needs unlocked and made available, not just for the present but for future generations of herbal practitioners. An initiative was launched at the 3rd SSHM research conference in April 2008 to gather and collate case histories. Herbalists who are willing to be involved in this crucially important work should contact the authors.

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