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• Research Article

Developing the criteria for evaluating quality of individualization in homeopathic clinical trial reporting: a preliminary study

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OBJECTIVE: This study describes the development of a preliminary version of an instrument that attempts to assess the quality of reports of individualized homeopathic prescriptions in clinical trials and observational studies.

METHODS: A multidisciplinary panel of 15 judges produced an initial version of the instrument through iterative Delphi rounds and pilot-tested the instrument on five clinical trials. Later they assessed, under blind conditions, the individualization quality of 40 randomly-selected research reports. The final version of the instrument included six criteria. These items were scored consistently by all the raters regardless of background.

RESULTS: The instrument appeared to have adequate face and content validity, acceptable internal consistency or reliability (Cronbach's α 0.606 – 0.725), significant discriminant validity (F = 398.7; P < 0.000 1), moderate interrater reliability (Fleiss κ 0.533), agreeable test-retest reliability (Cohen's κ 0.765 – 0.934), moderate sensitivity (0.4; 95% confidence interval 0.253-0.566), and high specificity (1.0; 95% confidence interval 0.891-1.000).

CONCLUSION: The initial data suggest that this instrument may be a promising systematic tool amendable for further development.

KEYWORDS: clinical trials; consensus; Delphi; homeopathy; individualization; reliability; validity

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1 Introduction

Since the inception of homeopathy, individualization of remedies has been a pivotal as well as debatable concept. Individualized (classical) homeopathy is considered by its proponents as the most effective method that adheres to original tradition[1], but is also a controversial form of

therapy[2]. In individualized homeopathy, following a conventional diagnosis, the choice of remedy is based solely on matching the patient's symptom picture with the 'remedy picture'[2]. Most of the empirical literature concerning this subject matter is ambiguous and inconclusive. Consequently, subsequent development of homeopathy evolved as isopathy, clinical homeopathy, polypharmacy, complex homeopathy, and same formula in all patients[2,3]. The 1997 meta-analysis by Linde *et al*[4] found no evidence that individualized homeopathy was superior to other forms of homeopathy.

Though previously considered to be 'methodologically more difficult' to run, and to replicate trials of individualized homeopathy in a scientifically rigorous fashion[2], in the last decade, there has been a considerable increase in the number and quality of randomized controlled trials (RCTs) of individualized homeopathic practice[5]. Systematic reviews and meta-analyses have also suggested individualization as one of the key components affecting the combined estimates of study effects. Thus, clinical trials have already pointed to the need for consensus and definition regarding 'good quality homeopathy'[2,6]. Recently, some researchers have taken initiatives to develop homeopathic prescribing indicators[7] and systematic outcome assessment tool, namely Hering's Law Assessment Tool following homeopathic intervention[8,9]. However, there exists little empirical evidence that substantiates an evaluative instrument for the quality of homeopathic individualization. To our knowledge, this is the first endeavour to do so.

2 Materials and methods

The Delphi technique is an iterative and sequential, multistage, flexible, group-communication process for forecasting and decision-making purposes to obtain informed anonymous agreement and consensus among a panel of experts in the field on a particular issue or problem[10-12]. The objective is to derive quantitative estimates through qualitative assessment of evidence[13] through a structured, well-designed multiple sequential administration of survey questionnaires augmented with continuous summary feedback of aggregated responses of a panel of experts; thereby minimizing the liabilities of individual expert decision[10-12]. Experts are qualified and experienced professionals having relevant knowledge and expertise about a particular issue or problem[10-12]. The advantages include simplicity, flexibility, in-depth anonymity, controlled feedback, statistical group response, time and cost constraints, confidentiality, objectivity, and accuracy[10]. The disadvantage is indifference of experts and consequent elimination from the panel[10-12].

2.1 Design

The first round survey was planned to commence with open-ended questions inviting free-form suggestions and recommendations from the experts, followed by subsequent iterative rounds of close-ended questions, then another final round inviting suggestions to modify the provisional instrument. Extensive efforts were made to include all the probable elements identified in the literature review. Consensus to achieve was defined 'a priori' as ≥ 85% frequency of endorsement and Fleiss' kappa (κ) observed agreement between moderate to almost perfect, i.e., 0.41 and 1.00 (poor agreement: less than 0; slight agreement 0.01-0.20; fair agreement: 0.21-0.40; moderate agreement: 0.41-0.60; substantial agreement: 0.61-0.80; and almost perfect agreement: 0.81-1.00)[14].

2.2 Expert recruitment and profiles

Participants were selected for their expertise, rather than being a sampling representative for statistical purposes. Invitation and participation in the Delphi process were completed via email outlining aim, likely time commitment and processes. Those who did not respond to the initial invitation were emailed again 5, 10, and 15 d after the initial invitation. All participants were allocated with a random identification number for reporting and collation of results. Demographic data regarding the participants' profession, qualifications, employment, designation and contact details were recorded. They were invited to provide their consent to be considered as a member of Delphi panel in presentations and publications arising from this research. All participants who accepted the invitation to participate in the Delphi process were invited to complete each and every Delphi round, regardless of participation in the previous rounds unless they withdrew from the Delphi.

In order to meet the study goal, a total of 20 experts from three relevant domains – practice, teaching, and research – were invited. Experts were chosen to ensure diverse viewpoints within the scholarly, research, and clinical perspectives. Clinicians were required to have at least 10 years of practicing experience after graduating from homeopathic schools; academicians were required to have postgraduate degrees in homeopathy and at least 10 years of teaching experience in homeopathic schools; and the researchers were required to have at least ten peer-reviewed research papers published in reputed journals. Fifteen experts, five from each background, accepted the invitation and agreed to take part in the study; others remained silent in spite of repeated reminders by telephone and email (Table 1).

2.3 First-round Delphi

Following the 'Classic Delphi' method[15], the first round was qualitative in nature. A brief preamble was provided concerning the aim of the survey, definition of key terms, likely time commitment, the plan for 3-4 rounds of input as well as the necessity of completing all rounds. As circumstances might change from that of the initial recruitment, participants were asked to contact the