Homeopathy (2017) ■, 1–9

http://dx.doi.org/10.1016/j.homp.2017.07.003, available online at http://www.sciencedirect.com

ORIGINAL PAPER

Model validity of randomised placebo-controlled trials of non-individualised homeopathic treatment

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Background: **The comprehensive systematic review of randomised placebo-controlled trials (RCTs) in homeopathy requires examination of a study's model validity of homeopathic treatment (MVHT) as well as its risk of bias (extent of reliable evidence).**
Objective: **To appraise MVHT in those RCTs of non-individualised homeopathy that an associated investigation had judged as 'not at high risk of bias'.**
Design: **Systematic review.**
Methods: **An assessment of MVHT was ascribed to each of 26 eligible RCTs. Another 49 RCTs were ineligible due to their high risk of bias.**
Main outcome measures: **MVHT and the prior risk of bias rating per trial were merged to obtain a single overall quality designation ('high', 'moderate', 'low'), based on the *GRADE* principle of downgrading.**
Results: **The trials were rated as 'acceptable MVHT' (N = 9), 'uncertain MVHT' (N = 10) and 'inadequate MVHT' (N = 7); and, previously, as 'reliable evidence' (N = 3) and 'non-reliable evidence' (N = 23). The 26 trials were designated overall as: 'high quality' (N = 1); 'moderate quality' (N = 18); 'low quality' (N = 7).**

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Received 1 February 2017; revised 23 June 2017; accepted 31 July 2017

Please cite this article in press as: Mathie RT, et al., Model validity of randomised placebo-controlled trials of non-individualised homeopathic treatment, Homeopathy (2017), http://dx.doi.org/10.1016/j.homp.2017.07.003

Conclusion: **Of the 26 RCTs of non-individualised homeopathy that were judged 'not at high risk of bias', nine have been rated 'acceptable MVHT'. One of those nine studies was designated 'high quality' overall ('acceptable MVHT' and 'reliable evidence'), and is thus currently the only reported RCT that represents best therapeutic practice as well as unbiased evidence in non-individualised homeopathy. As well as minimising risk of bias, new RCTs in this area must aim to maximise MVHT and clarity of reporting.** *Homeopathy* (2017) ■, 1–9.

Keywords: Model validity; Non-individualised homeopathy; Randomised placebo-controlled trials; Risk of bias; Systematic review

Background

Our programme of systematic reviews and meta-analyses of randomised placebo-controlled trials (RCTs) in homeopathy includes examination of each eligible trial's risk of bias as well as of its model validity (MV). The latter attribute reflects the concordance between the trial design and ideal practice for the intervention under investigation, and is a key facet of study quality in RCTs of complementary/alternative medicine (CAM) therapies such as homeopathy.[1–3] We have previously reported our evaluations of RCTs of individualised homeopathic treatment, presenting the findings in connected papers.[4–6] We concluded that an individually prescribed homeopathic medicine may have a small treatment effect beyond that of placebo; however, decisive interpretation was undermined by the paucity of high-quality evidence.[4,6]

The present paper focuses on placebo-controlled RCTs of *non*-individualised homeopathic treatment. Trials of this nature comprise the majority of the RCT literature in homeopathy.[7] Akin to a conventional drug trial, these are studies in which the same homeopathic medicine (or its corresponding placebo) has been given to each of the trial participants. The in-depth, individualised, homeopathic prescribing approach is therefore not involved. Instead, non-individualised homeopathy trials have some basis in *clinical homeopathy*, in which a single medicine, or combination of medicines, is prescribed to an individual patient on the basis of a specified somatic symptom or set of symptoms.[8] The medicine may be a single traditional homeopathic remedy (e.g. *Arnica*), or a formulation of several remedies that is either a proprietary medicine ('complex medicinal product') or a unique formulation prepared for the purposes of the research. Alternatively, the single medicine may be a homeopathic nosode based on the principle of isopathy ('the use of medicines derived from a causative agent of the disease itself, or from a product of the disease process, to treat the condition'[8]).

The extent to which these several modes of homeopathy are successfully reflected in RCTs of non-individualised treatment is the subject of the present paper. As previously,[5] we assess model validity of homeopathic treatment (MVHT), defined as the extent to which a homeopathic intervention and the main measure of its outcome, as implemented in an RCT, reflect best clinical practice in homeopathy.

Objective: To appraise MVHT in the RCTs of non-individualised homeopathy which, in an associated investigation,[9] were judged to be not at 'high risk of bias'. Through this approach, we aimed to identify the *overall* high-, moderate- and low-quality evidence in RCTs of non-individualised homeopathic treatment.

Methods

Inclusion criteria for RCTs

We applied our MVHT assessment method (which was designed to examine RCTs of either individualised or non-individualised homeopathy) to peer-reviewed papers reporting randomised, placebo-controlled trials of non-individualised homeopathic treatment, published up to and including 2014. Through formal literature search methods, 110 records were identified as being potentially eligible for systematic review in this RCT category: after application of pre-defined exclusion criteria, 72 records (reporting a total of 75 RCTs) remained eligible for systematic review.[9] Of those 75 RCTs, 49 were rated as 'high' risk of bias (relevant details in Appendix 1)[9]; the remaining 26 RCTs ('uncertain' or 'low' risk of bias) were therefore the material for the present study on MVHT (details, including reference citations,[10–35] in Table 1).

Assessment of model validity

The development of our criteria-based method for MVHT has been described in detail elsewhere.[3,5] The assessment domains are as follows:

Domain I (Rationale): Would a significant body of accredited homeopaths support the rationale for the intervention used in the study?

Domain II (Principles): Is the specific intervention used consistent with homeopathic principles?

Domain III (Practitioner): Does the study have suitably qualified and experienced homeopathic practitioner input?

Domain IV (Outcome measure): Does the main outcome measure reflect the main effect expected of the intervention used?

Domain V (Outcome sensitivity): Is the main outcome measure capable of detecting change?

Domain VI (Follow-up): Is the length of follow-up for the main outcome measure appropriate to detect the intended effect of the intervention?

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