Charity Commission consultation: The use and promotion of complementary and alternative medicine: making decisions about charitable status
Response from the British Humanist Association

18 May 2017

About the BHA

The British Humanist Association (BHA) is the national charity working on behalf of non-religious people who seek to live ethical and fulfilling lives on the basis of reason and humanity. We promote Humanism, support and represent the non-religious, and promote a secular state and equal treatment in law and policy of everyone, regardless of religion or belief. Founded in 1896, we have around 55,000 members and supporters, and over 70 local and special interest affiliates.

Our policies are informed by its members, who include eminent authorities in many fields, and by specialists and experts who share humanist values and concerns. These include world-leading scientists, and the Humanist Philosophers, a group composed of academic philosophers whose purpose is to inform BHA policy and to promote a critical, rational and humanist approach to public and ethical issues.

Our position

It is fundamental that charities must be able to demonstrate public benefit from their activities that is not offset by countervailing detriment. In our view organisations which provide or promote the use of so-called 'complementary and alternative medicines' ('CAM') that already have or are seeking charity status should be required to meet this test no less than any other applicant organisation. They must demonstrate that their treatment is efficacious in advancing health over and above taking no action or taking a placebo, or there is a strong prospect that such efficacy could be established through research (for example, during the development of new drugs). There is often insufficient evidence supporting the efficacy of such treatments, which should be both scientifically plausible and demonstrable. Organisations that do not meet this test cannot be seen as providing public benefit by advancing health. Indeed, when some organisations encourage patients to favour 'CAM' over peer-reviewed and scientifically tested conventional medicines, they can and sometimes do cause severe harm to patients and thus a public detriment. In general, therefore, 'CAM' organisations should not be registered as charities.

Response to consultation questions

Question 1: What level and nature of evidence should the Commission require to establish the beneficial impact of CAM therapies?

In a report published in 2010, the House of Commons Science and Technology Committee laid out a clear framework for assessing the beneficial impact of homeopathy.[1] We believe that this framework should be applied to all 'CAM' treatments and should be adopted by the Charity Commission as the basis for its decisions. The report concluded that all considerations of the 'efficacy of homeopathy should be derived from well designed and rigorous randomised controlled trials (RCT).' An RCT is a 'type of study in which participants are randomly assigned to one of two or more clinical

[1] House of Commons Science and Technology Committee, *Evidence Check 2: Homeopathy: Fourth Report of Session 2009–10*: https://www.publications.parliament.uk/pa/cm200910/cmselect/cmsctech/45/45.pdf

interventions.'[2] It was concluded that RCTs 'are the best way of determining whether a causal relationship exists between the treatment and an outcome'[3] i.e. whether such treatments could be said to have positive health benefits. The main purpose of an RCT is to isolate the effect of the treatment in the outcome of the study. This is achieved by randomly assigning research participants between two otherwise matched groups, one of which receives the potential treatment and the other a placebo: the participants - and preferably those administering the trial - are unaware who receives the treatment and who the placebo (this is known as 'double-blinding'). Thereby, the effect of the treatment can be isolated and measured. These RCTs should establish whether the level of efficacy is beyond that which would be expected of a placebo and the results should be published in an industry respected peer-reviewed medical journal such as *The Lancet* or the *BMJ*.

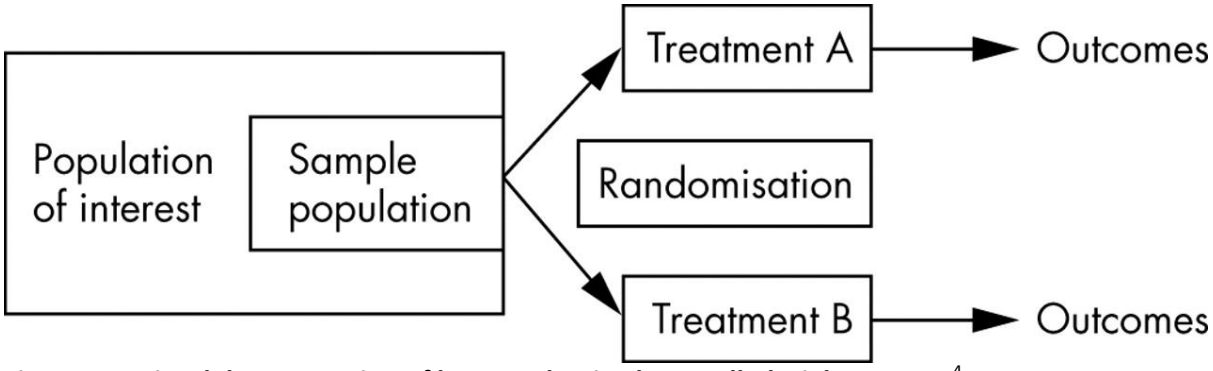

Figure 1: A visual demonstration of how randomised controlled trials operate.[4]

The overwhelming result of RCTs into the efficacy of 'CAM' treatments has suggested that there is no health benefit from most such medications. In 2002, a review of RCTs of homeopathy concluded that 'collectively they failed to provide strong evidence in favour [of health benefits]' and no evidence of an effect greater than that of a placebo.[5] It is the general view of the medical profession that 'many ['CAM'] treatments lack solid research on which to base sounds decisions. The dangers and possible benefits of many ['CAM'] treatments remain unproven.'[6] Without such evidence it is hard to see how any organisation that uses or promotes such treatments can be said to be promoting health or that such treatments are beneficial to the public at large. We recommend that the Charity Commission takes note of the Science and Technology Committee's framework and (subject to the following paragraph) only accepts claims on the basis of evidence derived from RCTs.

Sometimes the evidence from RCTs may be ambiguous or incomplete, for example during the development of new drugs. In such cases, if there is a degree of scientific plausibility (a credible understanding of how the medicine could work effectively) to the treatment and a strong prospect that efficacy could be established through further research, the Commission might consider provisional and time-limited registration pending completion of definitive RCTs.

It may be that a CAM is shown through a systematic review of RCTs to be effective at promoting health and therefore an organisation promoting it could be considered for charitable status. However, in these instances the treatment would generally become accepted as part of mainstream medicine, such as hypnotherapy in the treatment of irritable bowel syndrome, and would no longer be considered a 'CAM' treatment.[7] Thus, by definition a 'CAM' treatment is non-efficacious.

---

[2] Akobeng AK, 'Understanding randomised controlled trials'. *Archives of Disease in Childhood*, 2005; 90:840-844: http://adc.bmj.com/content/90/8/840

[3] *Evidence Check 2: Homeopathy: Fourth Report of Session 2009–10*, p7.

[4] The basic structure of a randomised controlled trial. 'Understanding randomised controlled trials'

[5] E Ernst, 'A systematic review of systematic reviews of homeopathy', *British Journal of Clinical Pharmacology,* 2002 Dec: 54 (6), p577-82: https://www.ncbi.nlm.nih.gov/pubmed/12492603

[6] Syed Amin Tabish, 'Complementary and Alternative Healthcare: Is it Evidence-based?', *International Journal of Health Sciences,* 2008, Jan, 2(1): V-IX: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068720/#

[7] Good Thinking Society ,'Charity Commission considers 'CAM' Chairities', 23 April 2017:

Question 2: Can the benefit of the use or promotion of CAM therapies be established by general acceptance or recognition, without the need for further evidence of beneficial impact? If so, what level of recognition, and by whom, should the Commission consider as evidence?

No. General acceptance, subjective testimony or claims made on the basis of patient satisfaction are insufficient to establish that these treatments will offer the public at large any health benefits. The acceptance of beneficial health claims without evidence from RCTs could have harmful and unethical effects upon the public at large.

In its submission to the House of Commons Science and Technology Committee report on homoeopathy, the Academy of Medical Sciences stated of 'CAM' treatments in general:

> 'It needs to be emphasised that patient satisfaction is not in itself a sufficient estimate of clinical benefit. While it is very important that patients be satisfied with the efforts made on their behalf, it is at least equally important that they should obtain objective benefit. The two do not always go together. For example, patients with peripheral vascular disease, if they go to a practitioner who allows them to continue smoking will show a high patient satisfaction although their outcome will be poor. In contrast, if they are made to stop smoking they are likely to be dissatisfied but their outcome will be much better.'[8]

It is possible that patients may experience positive changes in their health whilst using a 'CAM' treatment, and this may lead to a general recognition of some positive outcomes. However, such experiences are highly subjective and cannot be used to establish causation. In the view of the medical profession these health benefits are unreliable, likely to be small and short-lived.[9] Patients could also just be experiencing 'regression to the mean', whereby their symptoms (e.g. a cold) would have naturally gone away without their having taken the 'CAM' treatment. This is therefore an unreliable basis for accepting that they provide a public benefit.

Research into 'CAM' treatments has historically focused on their efficacy, not on their safety, and it remains a largely unregulated area of medicine. The Wellcome Trust investigated 14 'CAM' treatments claimed to alleviate pain and found adverse effects in half.[10] A 2010 study, published in the *Archives of Disease in Childhood*, looked at 39 separate incidences where adverse side effects caused by 'CAM's were reported to the Australian Paediatric Surveillance Unit. In two thirds of cases the side effects were rated as 'severe, life threatening or fatal.'[11] In both of these studies patients underwent these treatments because there was a general acceptance of their efficacy, but this was insufficient to protect their health. In its guidance on decisions on charitable status the Charity Commission states it will consider any potential harm these treatments might cause. Giving charity status to organisations that use or promote 'CAM' on this basis is likely to strengthen the public impression that such treatments are safe and effective when some are not safe and few, if any, effective. The case against charitable status is strengthened if it would encourage patients to abandon conventional medications on which their health may depend.

It is increasingly considered unethical to prescribe placebos, or treatments that are not shown to be more efficacious than placebos, such as homeopathic remedies. In his submission to the Science and Technology Committee Dr Thallon, Medical Director of NHS West Kent stated:

---

http://goodthinkingsociety.org/charity-commission-consultation-on-cam-charities/

[8] *Evidence Check 2: Homeopathy:" Fourth Report of Session 2009–10*, p13.

[9] Edzard Ernst, 'Why I changed my mind about homeopathy', *The Guardian*, 3 April 2012: https://www.theguardian.com/science/blog/2012/apr/03/homeopathy-why-i-changed-my-mind

[10] Anna Wilkinson, 'Complementary medicine: ethics', *Nuffield council on Bioethics,* 2014, p10: http://nuffieldbioethics.org/wp-content/uploads/Complementary_medicine_FINAL_FL_paper-1.pdf

[11] Dominic Hughes, 'Alternative remedies "dangerous" for kids says report', *BBC News*, 23 December 2010: http://www.bbc.co.uk/news/health-12060507

> 'in principle, if you prescribe a drug which you know to have no clinical efficacy on a basis which is essentially dishonest with a patient, I personally feel that that is unethical behaviour.'

The World Medical Association's Declaration of Lisbon (1981) states the fundamental position that patients have the right to accept or refuse treatment after receiving adequate information.[12] Such information should include the likelihood of the treatment being effective. To tell a patient that a treatment is as efficacious as a placebo is likely to mitigate any placebo effect, whereas to conceal this fact would be to not provide the patient with adequate information about their treatment. Allowing organisations that use or promote 'CAM' treatments to register as charities, on the basis of a general impression of health benefits, would legitimise practices that are ethically questionable and encourage financial support of bodies promoting them.

Question 3: How should the Commission consider conflicting or inconsistent evidence of beneficial impact regarding CAM therapies?

There is a wide range of therapies that fall into the category of 'CAM', such as acupuncture, homeopathy, chiropractic, osteopathy, and herbalism, with different levels of evidence of the efficacy of each. Assessing the strength of evidence in such cases may not currently be the expertise of the Charity Commission but such evidence is essential to the question, fundamental in charity law, of public benefit. We therefore recommend that the Charity Commission should appoint an expert panel to advise it on relevant aspects of applications for registration. Such a panel should be required to make use of a clear hierarchical framework of evidence in which the presentation of a systematic review of RCTs should be viewed as the best method of establishing beneficial effect, as recommended by the House of Commons Science and Technology Committee. Such a hierarchy would allow for the ranking of evidence, from RCTs to opinion, so as to indicate which should be given the most weight, as follows:

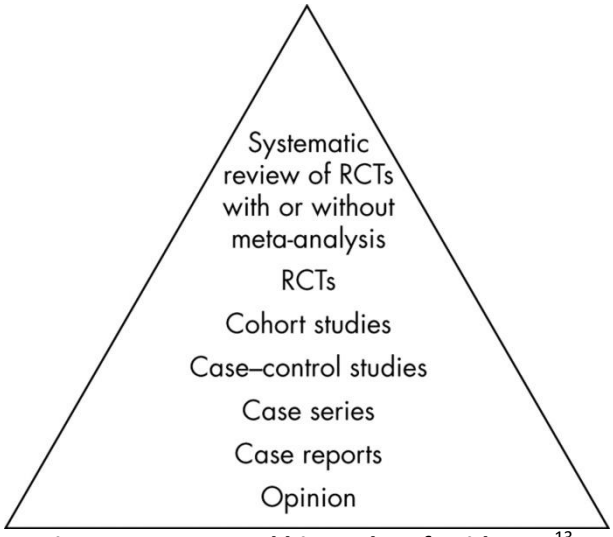

Figure 2: Suggested hierarchy of evidence.[13]

The panel can be assisted when there is conflicting or inconsistent evidence by requiring organisations to present a systematic review of the evidence in favour of their particular 'CAM'

[12] E Ernst, M H Cohen and J Stone, 'Ethical problems arising in evidence based complementary and alternative medicine' Symposium on evidence based medicine, *Journal of Medical Ethics*, 30, Issue 2: http://jme.bmj.com/content/30/2/156#xref-ref-21-1

[13] Hierarchy of evidence for questions about the effectiveness of an intervention or treatment. 'Understanding randomised controlled trials'

treatment, as well as adducing evidence from other sources. For example, using this hierarchy PJ Orrock and SP Myers were able to reduce the field of evidence on the efficacy of osteopathy in relation to Chronic Nonspecific Low Back Pain from 809 inconsistent accounts to two rigorous peer-reviewed RCTs[14] - both of which concluded that there was no benefit to the treatment compared to sham treatments or that could not be achieved through conventional exercise and physiotherapy. When considering conflicting information arising from an RCT the Charity Commission should instruct the panel to consider the following questions:

- Did the study ask a clearly focused question?
- Was the study an RCT and was it appropriately so?
- Were participants appropriately allocated to intervention and control groups?
- Were participants, staff, and study personnel blind to participants' study groups?
- Were all the participants who entered the trial accounted for at its conclusion?
- Were participants in all groups followed up and data collected in the same way?
- Did the study have enough participants to minimise the play of chance?
- How are the results presented and what are the main results?
- How precise are the results?
- Were all important outcomes considered and can the results be applied to … [the] population [at large]?[15]

The Cochrane Collaboration, the National Institute for Health and Care Excellence (NICE), and NHS Choices are good sources of information on the current state of RCT evidence into 'CAM' treatments that should be consulted.

Specifically in the case of homeopathy the evidence indicating that it has no health benefits is clear and consistent. In his submission to the Science and Technology Committee medical doctor and journalist Ben Goldacre stated:

> 'There have now been around 200 trials of homeopathy against placebos… and, taken collectively, they show that there is no evidence that homeopathy pills are any better than a placebo… it is not worth doing any more placebo controlled trials.'[16]

Therefore, homeopathic organisations should not be considered charitable organisations.

Question 4: How, if at all, should the Commission's approach be different in respect of CAM organisations which only use or promote therapies which are complementary, rather than alternative, to conventional treatments?

The approach should be no different. It may be that a therapy promoted as complementary rather than as an alternative to conventional medicine presents less harm to a patient. However, this does not necessarily follow, and at any rate, the judgement on charitable status lies principally in whether promotion of provision of the treatment can be said to be of public benefit, which must require that the treatment actually promotes health as it claims. Therefore, the distinction between treatments which are marketed as complementary rather than alternative is irrelevant.

Question 5: Is it appropriate to require a lesser degree of evidence of beneficial impact for 'CAM'

---

[14] Orrock PJ and SP Myers, 'Osteopathic intervention in chronic non-specific low back pain: a systematic review' *BMC Musculoskelet Disord*. 2013 Apr 9;14:129: https://bmcmusculoskeletdisord.biomedcentral.com/articles/10.1186/1471-2474-14-129

[15] 'Understanding randomised controlled trials'

[16] *Evidence Check 2: Homeopathy:" Fourth Report of Session 2009–10*, p21.

therapies which are claimed to relieve symptoms rather than to cure or diagnose conditions?

As above, the approach taken by the Charity Commission should be no different. Both in the case of 'CAM' remedies that claim to relieve symptoms and those that claim to cure an ailment, it must be established that the treatment has the beneficial impact that it claims to have. The only reliable way to establish if this is the case is through examining a systematic review of RCTs. Therefore, this should be considered the 'gold standard'[17] by which all 'CAM' treatments are assessed.

Question 6: Do you have any other comments about the Commission's approach to registering CAM organisations as charities?

We would like to draw the Charity Commission's attention to the work of the Good Thinking Society who has been successfully campaigning against 'CAM' treatments, specifically homoeopathy, being funded by the NHS. Only a handful of Clinical Commissioning Groups currently fund homeopathic treatments, with NHS Wirral and NHS Liverpool recently ceasing to support these remedies.[18] If the NHS does not consider 'CAM' treatments worth prescribing, the Commission can safely take the position that they cannot demonstrate sufficient public benefit to be worthy of the public subsidy and recognition that comes with charity registration.

The Charity Commission should take note of the criteria used by other organisations to assess the beneficial claims of 'CAM' medicines, most notably the Advertising Standards Authority (ASA) and the Committees of Advertising Practice (CAP). These standards protect consumers from false or misleading claims. CAP takes the position that proponents of 'CAM' treatments should not be able to make claims about the benefits of their treatments unless theys are medically qualified and/or the evidence of efficacy is robust. It recommends that 'if a[n advertisement] includes direct or indirect claims, then this will be subject to the same rules as any other claim… patient testimonials alone are unlikely to substantiate objective claims about the efficacy of a product or therapy.'[19] In the case of homeopathy the evidence did not meet guidelines on acceptable advertising for the treatment of any conditions. It would be inappropriate for the Charity Commission to allow organisations promoting 'CAM' treatments to register as charities, with all the reputational and financial benefits that brings, on the basis of claims that are deemed to be either misleading or too dangerous to the public to advertise.

Finally, we recommend that the Charity Commission also reviews how it assesses the public benefit of organisations whose sole primary purpose is to promote or teach 'creationism' and 'intelligent design' - whether registered under educational or religious charity objects. Non-scientific or un-evidenced theories should not be taught as science and such organisations should not be afforded the legal, financial, or reputational benefits that come with charity status. Indeed, the UK Department for Education no longer allows state-funded schools to teach creationism or intelligent design as scientifically valid, as this is deemed to fail the requirement for the curriculum to be 'balanced',[20]and all schools (state or private) are now downgraded by Ofsted if found to be teaching in this way. Therefore, we recommend that the Charity Commission adopts a similar framework, as recommended for CAM treatments, based upon the scientific methodology for assessing all claims to the public benefit for these organisations.

---

[17] 'Understanding randomised controlled trials'

[18] Good Thinking Society, 'NHS Homeopathic Spending': . http://goodthinkingsociety.org/projects/nhs-homeopathy-legal-challenge/nhs-homeopathy-spending/

[19] Committees of Advertising Practice, 'CAP position on Homeopathy', 25 April 2016: https://www.asa.org.uk/advice-online/health-homeopathy.html

[20] British Humanist Association, 'Government bans all existing and future Academies and Free Schools from teaching creationism as science', 18 June 2014: https://humanism.org.uk/2014/06/18/victory-government-bans-existing-future-academies-free-schools-teaching-creationism-science/

For more details, information and evidence, contact the British Humanist Association:

Richy Thompson
Director of Public Affairs and Policy
0781 558 636
020 7324 3072
richy@humanism.org.uk
www.humanism.org.uk

Date: 18 May 2017