

Research in complementary and alternative medicine (CAM) is confronted with the challenge that the established methodology of clinical research is often difficult to apply. However, even in conventional medicine scientific evidence is sometimes hard to accumulate, e.g. in rare diseases, children, or severely ill patients. The editorial of Frankovich, Longhurst and Sutherland discusses the usefulness of electronic medical records (EMR) in situations where other evidence is lacking. Can EMR provide a useful tool for CAM research?

Further examples enlightening the challenges around research in complementary medicine is the impossibility of blinding interventions or the difficulties to develop truly inert control conditions (e.g. in acupuncture). Therefore, discussion, debate, and consensus around methodological issues traditionally have played a prominent role in CAM research. The Society for Acupuncture Research consensus paper by Langevin et al. is an important contribution to the debate around acupuncture research.

Nonetheless, despite all these challenges, evidence for the effectiveness of CAM interventions is continuously accumulating. One of the latest examples is that rigorous clinical trials, such as the one from Sherman et al., have shown that yoga is an effective intervention for chronic back pain.

Finally, I would like to thank the experts who have taken the time to carefully read and comment these papers for the audience of FORSCHENDE KOMPLEMENTÄRMEDIZIN!

Frauke Musial, Tromsø

Acupuncture Research Strategies – the Society for Acupuncture Research White Paper

**Langevin HM, Wayne PM, Macpherson H, Schnyer R,
Milley RM, Napadow V, Lao L, Park J, Harris RE,
Cohen M, Sherman KJ, Haramati A, Hammerschlag R:
Paradoxes in acupuncture research: strategies for
moving forward. Evid Based Complement Alternat
Med 2011;2011:180805.**

In November 2007, the Society for Acupuncture Research (SAR) held an international symposium to mark the 10th anniversary of the 1997 NIH Consensus Development Conference on Acupuncture. The symposium presentations revealed the considerable maturation of the field of acupuncture research, yet two provocative paradoxes emerged. First, a number of well-designed clinical trials have reported that true acupuncture is superior to usual care, but does not significantly outperform sham acupuncture, findings apparently at odds with traditional theories regarding acupuncture point specificity. Second, although many studies using

animal and human experimental models have reported physiological effects that vary as a function of needling parameters (e.g., mode of stimulation) the extent to which these parameters influence therapeutic outcomes in clinical trials is unclear. This White Paper, collaboratively written by the SAR Board of Directors, identifies gaps in knowledge underlying the paradoxes and proposes strategies for their resolution through translational research. We recommend that acupuncture treatments should be studied (1) 'top down' as multi-component 'whole-system' interventions and (2) 'bottom up' as mechanistic studies that focus on understanding how individual treatment components interact and translate into clinical and physiological outcomes. Such a strategy, incorporating considerations of efficacy, effectiveness and qualitative measures, will strengthen the evidence base for such complex interventions as acupuncture.

Commentary – Terje Alraek, Tromsø, and Stephen Birch, Oslo

In 2011 the board of directors of the US based Society for Acupuncture Research (SAR) published an important paper 'Paradoxes in Acupuncture Research: Strategies for Moving

Forward' [1] outlining their findings about research on acupuncture, what they perceive to be paradoxes in those findings and strategies for addressing these issues so that research on acupuncture can move forward. This is an important and timely paper. For the most part we are in agreement with their conclusions and recommendations, but there are some issues that we feel need additional commentary.

The authors describe two paradoxes: '(1) A large number of well-designed clinical trials have reported that true acupuncture is superior to usual care, but does not significantly outperform sham acupuncture, findings apparently at odds with traditional theories regarding acupuncture point specificity and needling technique. (2) While many studies in animal and human experimental models have reported physiological effects that vary as a function of needling parameters (e.g., needle insertion depth, mode of stimulation), the extent to which these parameters influence therapeutic outcomes in clinical trials is unclear.'

We wonder whether calling these two issues 'paradoxes' might be misleading and potentially weaken acceptance of the arguments in the paper. One could argue that the first is rather a difference of interpretation between skeptics of acupuncture who believe that the lack of difference is because the effects of acupuncture are primarily placebo [2] and other researchers who point out that there are significant problems with sham acupuncture due to the fact that it is not inert and has a range of undefined physiological activity [3, 4]. One could argue that the second issue is rather due to the fact that there are insufficient studies of the right kind that can address the identified problem. The first issue then is one of interpretation of the data and the second that there has not been sufficient focus on acupuncture as it is practiced to inform how studies should be designed to investigate or expose the mechanisms by which it may work. This is all the more so for the more traditionally based styles of practice. We feel that the fact that the statements are questionably paradoxical does not detract from the arguments the authors present, rather it exposes additional arguments that perhaps could have been made which further strengthen their position.

The distinctions the authors made between 'non-specific components', 'specific non-needling components' and 'needling components' while useful do not seem sufficient. It is likely that there are important effects that can be due to how well the practitioner can interact with the patient and influence the qi with needling that are not adequately covered in these distinctions. Further, they do not distinguish between intended theory or technique-driven specific needling effects and non-acknowledged (and thus maybe unintended) non-specific effects of needling. We feel it would be helpful to identify a fourth component: 'non-specific needling components' [3]. It is important to mention this since this is an area that has created significant problems for the interpretation of the role of placebo in sham acupuncture studies and relates to the first 'paradox'. The purpose of performing a sham inter-

vention is trying to control for placebo effects, in the same way that the purpose of giving a placebo pill is to try to control for placebo effects. So far, no sham acupuncture therapy has ever been 'inert' [3], not even the non-penetrating needles [5, 6]. When these components are not separated, they are mistakenly seen to amplify the placebo effects in a sham trial [3, 7, 8] and thus can bias against the test therapy [7, 9, 10]. This is all the more important when the sham acupuncture also includes unknown active components of treatment that can specifically affect relevant physiological parameters [9]. This problem shows especially when the needling techniques of one system of acupuncture practice are used as though they cannot possibly work since they are so different than the test treatment needling methods, as is found with the choice of shallow needling methods as a sham control [10, 11]. The use for example of 'minimal' or 'superficial' needling as a sham control in trials of acupuncture exposes weaknesses in the knowledge of research teams vis-à-vis the practice of acupuncture. That fact that superficial needling may be an effective needling method has been known for almost 30 years [12]; it is a routine method of treatment in some systems of acupuncture, notably Japanese but also other systems has been known for a long time [13, 14]. We feel that it is thus useful to add this fourth needling component to ensure proper attention to this complex issue and strengthen the arguments underlying the issue the authors have identified as paradox one.

Part of this problem with the sham is, as the authors identify, due to not having a clear definition of acupuncture [1]. Another issue with the sham that the authors have identified is the recognition that acupuncture is a complex intervention [15, 16]. Evidence continues to accrue confirming this finding [17]. It would be helpful to examine additional areas to further document the complex nature of this intervention. For example, using biological measures and qualitative assessments of patient change, practitioner observations of those changes and how treatment is modified in an on-going process would be an important area to explore. It will also be important to bring patient perspectives more into the picture. Patients' descriptions of health changes after acupuncture treatment have been reported [18–21]. 'Such changes may be important, and further analysis of the relationship between such bodily experiences could lead to the development of hypotheses or models for how the acupuncture effect is mediated in complex bodily systems, and also contribute to development of outcome measures relevant for acupuncture studies' [20]. Another important area may be the potential role of consciousness in relation to needling sensations. There is increasing evidence from both descriptions of traditionally based systems of practice [22, 23] and clinical studies [24] of the possible influence of consciousness that perhaps highlights further the complex nature of acupuncture. The important point for acupuncture research is that for complex interventions research methods have yet to be fully developed and research

design carefully matched to testable hypotheses, where it may be very difficult if not impossible to control for placebo [25–27]. In other words sham trials may be inappropriate as a tool for testing acupuncture. This argument will likely increase in strength as evidence continues to develop about the nature of acupuncture as a complex intervention.

The issue of having unclear mechanisms by which acupuncture works is, as the authors describe [1], relevant in terms of designing studies that attempt to control for placebo effects [28, 29]. ‘For an intervention to have a credible chance of improving health or health care, there must be a clear description of the problem and a clear understanding of how the intervention is likely to work’ [26]. But this lack exposes another area: the need for more qualitative research investigating the nature of acupuncture practice so that more relevant physiological studies can be designed to test that practice or those practice methods. The conclusions of the paper [1] that it is better to proceed with research focusing on more pragmatic-type trials to examine effectiveness of acupuncture and physiological studies to examine mechanisms is similar to that drawn by Hyland in 2003 [30] and one that we strongly support. The design of sham acupuncture studies remains unclear, and the interpretation of them is even more difficult and fraught with mistakes. It is perhaps time to move on until we have sufficient clear evidence to try such studies again.

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Yoga Is an Effective Treatment for Chronic Low Back Pain

Sherman KJ, Cherkin DC, Wellman RD, Cook AJ, Hawkes RJ, Delaney K, Deyo RA: A randomized trial comparing yoga, stretching, and a self-care book for chronic low back pain. *Arch Intern Med* 2011;171: 2019–2026.

Background: Chronic low back pain is a common problem lacking highly effective treatment options. Small trials suggest that yoga may have benefits for this condition. This trial was designed to determine whether

yoga is more effective than conventional stretching exercises or a self-care book for primary care patients with chronic low back pain.

Methods: A total of 228 adults with chronic low back pain were randomized to 12 weekly classes of yoga (92 patients) or conventional stretching exercises (91 patients) or a self-care book (45 patients). Back-related functional status (modified Roland Disability Questionnaire, a 23-point scale) and bothersomeness of pain (an 11-point numerical scale) at 12 weeks were the primary outcomes. Outcomes were assessed at baseline, 6, 12, and 26 weeks by interviewers unaware of treatment group.

Results: After adjustment for baseline values, 12-week outcomes for the yoga group were superior to those for the self-care group (mean difference for function, -2.5 [95% CI, -3.7 to -1.3]; $P < .001$; mean difference for symptoms, -1.1 [95% CI, -1.7 to -0.4]; $P < .001$). At 26 weeks, function for the yoga group remained superior (mean difference, -1.8 [95% CI, -3.1 to -0.5]; $P < .001$). Yoga was not superior to conventional stretching exercises at any time point.

Conclusion: Yoga classes were more effective than a self-care book, but not more effective than stretching classes, in improving function and reducing symptoms due to chronic low back pain, with benefits lasting at least several months. Trial Registration clinicaltrials.gov Identifier: NCT00447668.

Kommentar – Andreas Michalsen, Berlin

Die Arbeitsgruppe um Karen Sherman, Daniel Cherkin und Richard Deyo aus Seattle, WA, beschäftigt sich schon seit vielen Jahren schwerpunktmäßig mit vergleichenden Wirksamkeitsstudien im Indikationsgebiet chronische Rückenschmerzen. Die Ergebnisse der jetzt vorgelegten dreiarmigen Vergleichsstudie zwischen Yoga, Stretching und einer «Self-care»-Gruppe, wurden bereits mit Spannung erwartet. In die Studie eingeschlossen wurden Patienten mit nur mäßig starken Beschwerden, erkennbar an den Baseline-Funktionswerten und dem geringen Gebrauch von Medikamenten. In den Ergebnissen zeigte sich, dass Yoga und Stretching effektiv und besser im Vergleich zu «self-care» die Funktion verbesserten, jedoch kein Unterschied zwischen beiden aktiven Interventionen bestand. Die Effekte waren insgesamt moderat, und für das zweite primäre Zielkriterium, «Beeinträchtigung durch Schmerz» fand sich kein signifikanter Unterschied zwischen den drei Gruppen. Bei den sekundären Zielvariablen zeigten sich homogen Yoga und Stretching der dritten Gruppe überlegen, wiederum ohne Unterschied zwischen den beiden aktiven Gruppen. In einem begleitenden Editorial von T.S. Carey [1] wird die Studie als ein sehr gutes Beispiel für «comparative effectiveness research» (CER) gelobt, insbesondere, da drei gebräuchliche Therapiemethoden verglichen wurden und die in die Studie eingeschlossenen Patienten wenig selektiert waren. Dem ist insgesamt zuzustimmen, allerdings sind auch Besonderheiten der vorgelegten Studie zu notieren, bevor zu generelle Rückschlüsse aus den Ergebnissen gezogen werden.

Zunächst sind die Art und Methode des eingesetzten Yoga und der Krankengymnastik/ Stretching zu betrachten. Eine ausführliche Beschreibung des Studiendesigns und der eingesetzten Verfahren wurde von den Autoren bereits se-

parat publiziert. Die Krankengymnastik war im zeitlichen Umfang mit 12 Klassen von je 75 min analog zur Yoga-Intervention gestaltet. 15 Dehnungsübungen wurden geübt, alle größeren Muskelgruppen waren einbezogen, und die Dehnungsendposition wurde für 60 s gehalten und einmal wiederholt. Zusätzlich wurden ein 5-minütiges aerobes Warm-Up sowie einige Muskelkräftigungen eingebracht. Täglich sollte 20 min zu Hause geübt werden. In der Yoga Gruppe wurde Vini-Yoga eingesetzt und im Hauptteil des Übungsprogrammes 5–11 Übungen (dehnende Asanas) durchgeführt, ergänzt durch spezifische Atemtechniken und Tiefenentspannung. Insgesamt wurden damit therapeutisch-methodisch Yoga und Stretching einander stark angenähert. Es verwundert daher kaum, dass sie sich als ähnlich wirksam erwiesen, repräsentieren damit aber nicht gängige Praxis. Nur wenige Physiotherapieformen beinhalten derzeit Dehnungen mit solcher Intensität. Andererseits wurden die meisten der bislang durchgeführten Studien zu Yoga bei Rückenschmerz mit Iyengar-Yoga durchgeführt, das sich von Vini-Yoga zweifellos unterscheidet. Dennoch sind die Ergebnisse in vielerlei Hinsicht interessant. Es zeichnet sich ab, dass die Dehnungskomponente der Asanas der Hauptmediator der Wirksamkeit sein könnte. Die Ergebnisse legen auch nahe, Dehnungen sehr viel stärker in physiotherapeutischen Ansätzen zu fokussieren. Die Wirksamkeit von Yoga als Therapie bei chronischen Rückenschmerzen erscheint nun insgesamt ausreichend belegt. Etwa zeitgleich wurde eine weitere Studie zur Wirksamkeit von Yoga bei chronischen unteren Rückenschmerzen in *Annals of Internal Medicine* publiziert [2]. In dieser pragmatischen Studie wurde Patienten in 39 Arztpraxen randomisiert entweder die Teilnahme an 12 Yoga Klassen angeboten oder ein Manual überreicht. Nach 3,6, und 12 Monaten zeigte sich im Vergleich in der Yoga Gruppe eine signifikant bessere Funktion. Es scheint nun an der Zeit Yoga als Therapie bei Rückenschmerzen im Gesundheitswesen zu etablieren.

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Clinical CAM Evidence in the Era of the Electronic Medical Record

Frankovich J, Longhurst CA, Sutherland SM. Evidence-based medicine in the EMR era. N Engl J Med 2011; 365:1758–1759.

Many physicians take great pride in the practice of evidence-based medicine. Modern medical education emphasizes the value of the randomized, controlled trial, and we learn early on not to rely on anecdotal evidence. But the application of such superior evidence, however admirable the ambition, can be constrained by trials' strict inclusion and exclusion criteria – or the complete absence of a relevant trial. For those of us practicing pediatric medicine, this reality is all too familiar. In such situations, we are used to relying on evidence at Levels III through V – expert opinion – or resorting to anecdotal evidence.

Commentary – Vinjar Fønnebo, Tromsø

Reluctance in CAM Research to Adopt the Randomized, Controlled Trial

Over the recent decades researchers in CAM have tried to accommodate critics of CAM by designing and performing a number of double-blind, placebo-controlled, randomized, controlled trials (RCTs) in homeopathy, acupuncture, and other CAM disciplines. Whether the treatment used in these trials reflected clinical practice was not a major concern. If the trials resulted in a statistically significant positive result, CAM practitioners were happy; but if the trials were negative, they could blame the lack of clinical relevance.

Pursuing this line of CAM research is approaching a dead end. There is a substantial gap between this research and the clinical experience of both patients and practitioners. CAM clinicians and some researchers are openly stating that neither the patients recruited to these trials nor the treatment given reflects the day-to-day practice of CAM [1]. The treatments are normally not given in isolation, and treatment is customized to the specific clinical presentation of the patient.

Conventional Medicine Has Never Fully Adopted the Randomized, Controlled Trial

Interestingly a recent 'Perspective' article in the *New England Journal of Medicine* brings up these challenges as relevant also to conventional medicine [2]. The example is taken from pediatric rheumatology. The authors identify problems with 'trials' strict inclusion and exclusion criteria' and 'complete absence of a relevant trial'. The pediatricians were faced with a clinical situation where no trial evidence was, and will probably never be, available, the clinical scenario was complex, and time was short. They were forced to rely on level III through V evidence [3] – expert opinion or anecdotes. No anecdotes were readily available, and a quick survey of colleagues (expert opinion) yielded no results.

The two major problems identified by these pediatric rheumatologists with regard to clinical trials are the major given

reasons for the dismal compliance with health technology assessments (HTAs), systematic reviews, and clinical guidelines in conventional medicine [4]. Clinical practice still seems to rely heavily on expert opinion and anecdotes, which also go by a different name – experience. Experience has, however, appropriately been frowned upon. It can be highly subjective, and has in the past not been sufficiently systemized. Conventional medicine has thus established the concept of evidence-based medicine with its strict hierarchy, while in practice going on, with some important exceptions, mostly as before.

Comparative Effectiveness – Whole System Research

The Institute of Medicine in the USA has defined comparative effectiveness research as 'the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels' [5]. This is the type of whole system research (WSR) that the pediatricians would have benefitted from, had it been available. Their clinical problem was, however, so rare that even a pragmatic clinical trial was unfeasible.

Most CAM practitioners find themselves in a similar situation as the pediatricians in the *New England Journal of Medicine* article. An appropriate treatment is to be applied to a patient in a clinical situation that is very uncommon. CAM practitioners often claim that they are giving individualized treatment; no two patients get the same. If that is the case, no trial research could ever guide them in their clinical decision-making. The clinical situation is, however, not unique, but is shared only by a small number of other patients. The best way to find the treatment of choice should then be the best use of experience. In case of the pediatricians, they started looking into their electronic medical records. CAM practitioners can up to now only try to retrieve their experience from own or others' memory.

Quality Registers

Parallel to the emergence of evidence-based medicine, there has been a proliferation of clinical quality registries, especially in the Scandinavian countries [6]. These registries have been established in parallel with the electronic medical record with the intent of informing clinicians within a specific field of medical practice. They have the great advantage of recording data in discriminate units. The variables are chosen thoughtfully with the purpose of informing clinical choice.

Sweden has established a number of such registries, and the author is personally involved in, among others, the Norwegian National Quality Registry of Spinal Surgery. This registry records, and thereby monitors, the clinical practice of spinal surgery. Most clinical quality registries include clinically relevant outcome data and can thus describe which treatment choices in similar patients yield the best clinical results

– no randomization, no blinding, but very clinically relevant. These registries have already changed clinical practice in Scandinavia in areas as diverse as spinal surgery [7] and choice of hip replacement material [8].

This system of clinical quality registries provides an opportunity of systematically building on previous clinical real-time experience. The experience is built on a high volume of previous clinical decisions, and the data can be analyzed taking into consideration a number of potential confounding variables. This can actually be compared to the use of propensity scores in epidemiological research [9].

Real-Time Use of EMR – Challenges

The pediatricians in USA, however, had no established quality register to consult for their clinical condition. Their only source was EMRs. Their hospital had, however, already used the Stanford Translational Research Integrated Database Environment (STRIDE) platform to store all patient data contained in the EMR in a format that enables immediate advanced text searching capability [10]. A cohort had already been established on patients with the condition under treatment: systemic lupus erythematosus (SLE). It took therefore only 4 h for a member of the clinical team to find and extract the appropriate data on 98 previous patients they needed. The clinical choice was made based on information from these 98 previous similar patients, and the child they were treating avoided the negative outcome they intended to prevent. In hindsight no one will ever ‘know’ whether the negative outcome would have happened at all, but they were able to make the clinical decision based on a systematic collection of previous experience.

The most important challenge with the EMR as a useful tool is the nature of how an EMR is constructed, allowing for a large part of the information to be recorded as free text strings. A second major challenge is the analytical capacity and user-friendliness of this system. Finally, a third major challenge is the lack of a national or international standard for EMRs that prevents accumulation of large data sets.

Hope for a Common Understanding

Coming back to where we started: How does this apply to clinical CAM research?

Clinical CAM practice is typically seen as a whole system intervention where a number of treatments are applied simultaneously customized to the individual clinical situation of the patient at hand. Although double-blind, placebo-controlled, randomized, controlled trials are relevant also in this situation, they will mainly be useful only to determine if a specific tool of the trade can be improved. The most relevant clinical question will be to determine which ‘package of care’ to apply to this patient. Although most CAM practitioners claim they are giving ‘individualized’ treatments, what they really are applying is standardized treatment. The standardization is, however, made on a small unit of similar patients, quite comparable to the situation the pediatricians were in with their SLE patient.

This ‘Perspective’ article demonstrates that when the units of similarity are small, there probably will be no ‘politically acceptable’ evidence base to build on. It is necessary and legitimate to rely on systematically collected experience; there will probably never be anything else. With the accelerating subclassification of diseases and conditions with regard to genetic information, there might come a time when no ‘units of similarity’ will be large enough for trials as we now see them. The common challenge shared by the future of conventional medicine and CAM will be to determine how best to utilize the experience we are constantly building.

My prediction will be that the EMR will be developed to collect information in a more analyzable format. Not only will practitioners be able to use them as quality registers, but real-time analysis to guide current treatment choices will also be possible. If we add to this a searchable video record of the patient and the consultation, one could envision a total transformation of the systematic building of experience. What the institutional review boards and data-inspecting authorities will say is a completely different matter ...

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