A strong evidence base

Dr Ava Lorenc and Professor Nicola Robinson, from London South Bank University, provide an introduction to research and explain its importance for the therapy industry

Although we all know the benefits of complementary therapies for our clients, meeting the increasing demand for evidence to prove their effectiveness and safety is vital for the future of the therapy industry. It is a complex field, but learning to access, understand and use research can help to provide support and backing for your own therapy work, while helping to further support integrated healthcare by allowing stronger connections to be built with other healthcare professionals who value evidence-based medicine.

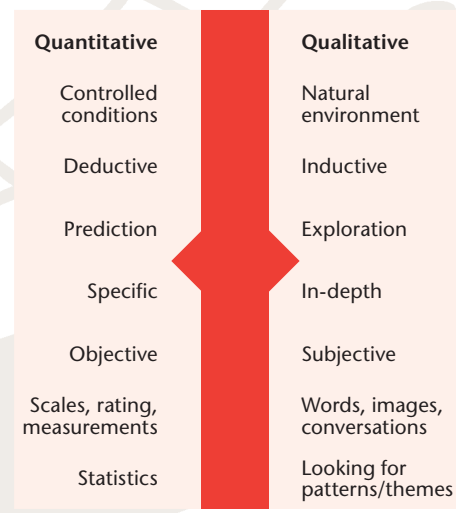
Research – what it is and key types

Research involves collecting and analysing data, and drawing conclusions. It is usually either evaluative, for example, determining if a therapy treatment works, or descriptive, which would typically explore people's experiences and perceptions. In addition, audit and evaluation may come under the heading of research. A useful method to monitor and improve your practice,[1-4] audit measures quality in existing healthcare, and evaluation measures the impact of a service.

Research can take many forms:

- **Case studies** – a report of a single person's treatment, or course of treatments. A case series would involve a series of related case studies for a number of people, usually all with the same health condition and treatment, for example 11 clients with schizophrenia given 10 weekly sessions of acupuncture treatment.[5]
- **Action research** – research done 'in action'; the practitioner does the research while they are performing the intervention, for example, volunteer community researchers providing an intervention and assessing it.[6]
- **Surveys** – asking people to complete questionnaires for descriptive purposes, for example, a survey of acupuncturists to find out details of how they practise.[7]
- **Basic science experiments** – usually based in a lab and using animals or cells.
- **Trials** – testing to see if an intervention works by giving a treatment to a group of people and assessing outcomes, for example, autogenic training for people with sleep problems.[8] This can include randomised controlled trials, case-control studies, and cohort studies. As trials are likely to be the most common form of research complementary therapists are interested in, that will be the focus of this article.
- **Observational studies** – observing the effect a treatment has on a group of people, for example, the use of ear acupuncture for hot flushes.[9]
- **Qualitative research** – the in-depth study of an issue, usually using interviews or focus groups, and often exploratory, for example, investigating the attitudes and beliefs of parents and conventional practitioners regarding complementary medicine.[10]
- **Systematic reviews** – systematically reviewing all the available evidence on a topic, for example, a review of shiatsu and acupressure.[11] Meta-analyses involve statistically combining all the available evidence on a topic.

Within these study designs, a range of research methods can be used. Although a little simplistic, you can place research methods on a scale – from quantitative 'hard science', to qualitative, exploratory research:



Challenges for CAM research

Research in complementary and alternative medicine (CAM) has particular challenges. Usually, trials would use a control treatment, such as a 'sham' or 'placebo' treatment, most commonly, sugar pills in pharmaceutical research, to find out whether a particular intervention has a significant effect over factors such as extra attention and resting, or the action of taking a pill. However, for

most CAM it is challenging or impossible to design a sham treatment.

An alternative study design is to compare conventional treatment with CAM, or to compare conventional treatment plus CAM with conventional only. Comparative effectiveness studies[12] are often used for these study designs to compare two types of treatment, for example, chemotherapy alone compared with chemotherapy plus reiki.

In addition, many CAM are 'complex interventions', for example, an acupuncturist providing acupuncture treatment, lifestyle advice and diet advice, or a programme that combines exercise and dietary advice. These may require specialist study designs, the most common of which is a pragmatic design where the intervention is based on that used in practice, rather than being standardised.[13] The Medical Research Council (MRC) has produced some excellent guidance on evaluating complex interventions.[14]

Another challenge is that it may not be possible to identify a primary outcome (the main effect expected from the treatment), as the therapy may have multiple, unpredictable effects, which could be different for each individual. This can be dealt with by using patient-generated outcome measures, such as MYMOP (Measure Yourself Medical Outcome Profile), which ask the client to specify what the most important outcome for them is.[15,16]

Why therapists need research

There is an increasing demand to prove the effectiveness and safety of complementary therapies – and learning to access, understand and use research also helps to build a solid foundation for your own practice. Understanding the evidence base for complementary therapies helps you decide what may be an appropriate approach for a client with specific set of symptoms, so you can provide a more individual, therapeutically effective treatment plan.

Evidence-based medicine (EBM) has been defined as integrating individual clinical expertise and the best external evidence.[17] In clinical practice, practising EBM involves exploring the evidence base for the particular condition and therapy, choosing the highest quality research and using this, alongside your clinical expertise and client input, to inform the treatment choice.

A strong evidence base for your therapy will help you and your profession to build connections with other healthcare professionals, in particular NHS professionals who are often mainly interested in EBM. By learning the language of research and familiarising yourself with the evidence base, you can communicate better with other professionals.

In many respects, the future of complementary therapy depends on the evidence base, in terms of financial support from clients and commissioners, support for

NHS-provided therapies and support from individual healthcare practitioners who may refer to you. If you are considering applying for funding, putting together a business proposal, or thinking about working within the NHS, research will help to provide support and backing for your therapy, and assessing the quality of the research is imperative to ensure that you have a strong case.

Accessing and assessing research

Finding research can seem a daunting task, with thousands of journals, hundreds of databases and a plethora of search engines. Research is published as articles or papers in journals, which can be online or printed, and are accessible through databases, which are online.

Here are the key steps in finding and using evidence:

1 Search the databases

- The first step is to search the databases to find relevant articles. Some of the common databases are Pubmed (www.ncbi.nlm.nih.gov/pubmed), Science Direct (www.sciencedirect.com), and NHS Evidence (www.evidence.nhs.uk). Subscription-only databases include Ebsco host (http://search.ebscohost.com) and Ovid (http://ovidsp.ovid.com). Google scholar (http://scholar.google.co.uk) is also useful, but should be used with caution because it is not an academic database, only searches certain journals and has limited search functions.
- You can also go straight to the journals, although these are included in the databases above. Some journals of interest include:
  - Alternative Therapies in Health and Medicine;
  - BMC CAM;
  - Complementary Therapies in Clinical Practice;
  - Complementary Therapies in Medicine;
  - European Journal of Integrated Medicine;
  - Forschende Komplementärmedizin;
  - Journal of Alternative and Complementary Medicine;
  - Journal of Complementary and Integrative Medicine; and
  - specific therapy journals.
- When looking for articles, it is important to think carefully about what you are searching for, as you will need to use keywords, just as you would when using Google. For example, if you want to find evidence for the use of aromatherapy for sleep problems, you might search for 'aromatherapy' or 'essential oils', and 'sleep' or 'insomnia'.

2 Read the abstracts of the papers you find to see if they are of use to you

- An abstract is basically a summary of the paper [Figure one]. A number of points to consider include:
  - Whether the treatment used is relevant to your work;
  - Which health condition is being studied and if this is appropriate for your purposes; and
  - How old the study is, with more recent studies potentially being the most relevant.

3 Find the full text of the articles you are interested in

- Once you have a list of articles you are interested in, you then have to get hold of the full text of these papers. Some open access journals publish the full text online for free (the researchers pay a fee for this); for others, you will have to pay, unless you are part of an organisation, such as a university, which pays an annual subscription for the journal. For a small fee, your local library may be able to obtain photocopied articles (for academic use only).
- Key open access journals are BMC CAM (www.biomedcentral.com/bmccomplementalternmed), BMJ (www.bmj.com), and Cochrane reviews (www.thecochranelibrary.com).
- If you are a student or employee of a university, the library will be able to give you guidance on how to access journals.

www.fht.org.uk

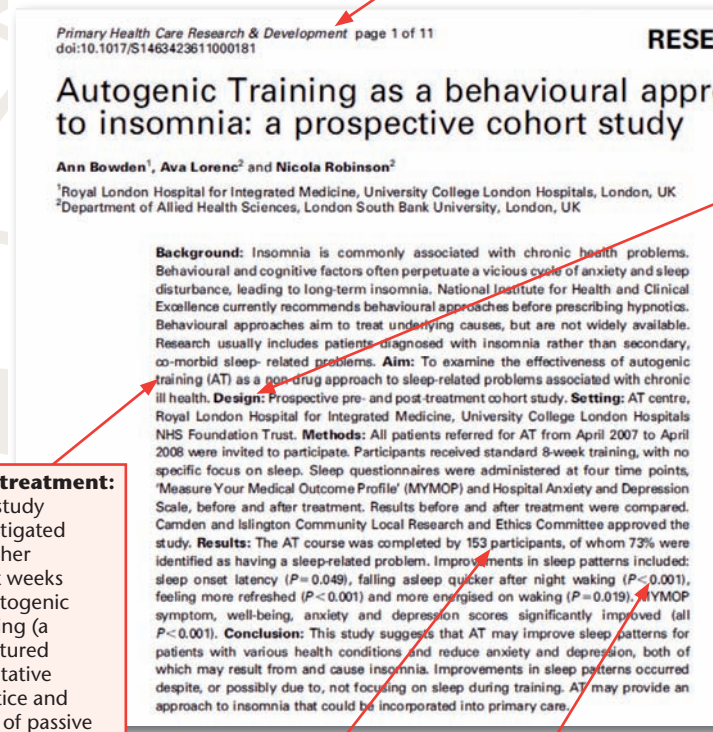
4 Assess the evidence

- Once you have the articles, you need to assess the quality of the research. This can be complex, but a few things to look for are:
  - Whether the study adds anything to the existing literature, and whether the findings were novel.
  - The type of study, and whether the study design was the right one for the question being studied. Systematic reviews and meta-analyses tend to be the highest form of evidence because they bring together the evidence from a large number of studies and evaluate their quality, with randomised trials considered the next best form, followed by cohort studies, case control studies and cross-sectional studies.
  - Who the study was about; how the participants were recruited, and the size of the study – in general, the more participants, the more reliable the study.
  - If the study tried to evaluate the effectiveness of a treatment; whether an appropriate control group was used (a group who didn't receive the treatment), and, if so, whether the two groups were as similar as possible. Non-randomised trials are more likely to be biased as there may be differences between the groups.
  - Whether the follow-up period was long enough and how many people finished the study. If too many dropped out, there may be reasons for this that affect the results, for example, maybe they experienced side effects from the intervention.
- There is a lot of guidance on how to appraise research, with one of the best being the BMJ series, How to Read a Paper (www.bmj.com/about-bmj/resources-readers/publications/how-read-paper) or the book, How to Read a Paper: The Basics of Evidence Based Medicine.[18]

Breaking down an abstract to its key components

Figure 1: How to read an abstract

The journal gives an idea of the quality of the paper



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RESEARCH

Autogenic Training as a behavioural approach to insomnia: a prospective cohort study

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Background: Insomnia is commonly associated with chronic health problems. Behavioural and cognitive factors often perpetuate a vicious cycle of anxiety and sleep disturbance, leading to long-term insomnia. National Institute for Health and Clinical Excellence currently recommends behavioural approaches before prescribing hypnotics. Behavioural approaches aim to treat underlying causes, but are not widely available. Research usually includes patients diagnosed with insomnia rather than secondary, co-morbid sleep- related problems. **Aim:** To examine the effectiveness of autogenic training (AT) as a non-drug approach to sleep-related problems associated with chronic ill health. **Design:** Prospective pre- and post-treatment cohort study. **Setting:** AT centre, Royal London Hospital for Integrated Medicine, University College London Hospitals NHS Foundation Trust. **Methods:** All patients referred for AT from April 2007 to April 2008 were invited to participate. Participants received standard 8-week training, with no specific focus on sleep. Sleep questionnaires were administered at four time points, 'Measure Your Medical Outcome Profile' (MYMOP) and Hospital Anxiety and Depression Scale, before and after treatment. Results before and after treatment were compared. Camden and Islington Community Local Research and Ethics Committee approved the study. **Results:** The AT course was completed by 153 participants, of whom 73% were identified as having a sleep-related problem. Improvements in sleep patterns included: sleep onset latency ($P = 0.049$), falling asleep quicker after night waking ($P < 0.001$), feeling more refreshed ($P < 0.001$) and more energised on waking ($P = 0.019$). MYMOP symptom, well-being, anxiety and depression scores significantly improved (all $P < 0.001$). **Conclusion:** This study suggests that AT may improve sleep patterns for patients with various health conditions and reduce anxiety and depression, both of which may result from and cause insomnia. Improvements in sleep patterns occurred despite, or possibly due to, not focusing on sleep during training. AT may provide an approach to insomnia that could be incorporated into primary care.

The treatment: The study investigated whether eight weeks of autogenic training (a structured meditative practice and state of passive awareness, used as a stress management technique to promote relaxation) could help people experiencing sleep problems as a result of chronic ill health.

Sample size: In general, the more participants used, the better, with 153 participants a strong sample size.

Results: Although it is not possible to explain p values in a sentence, because these are smaller than 0.05, these p values show that the results are statistically significant, meaning they are unlikely to have occurred by chance.

Study design: A cohort study tests to see if an intervention works by giving a treatment to a group of people and assessing outcomes. Sleep questionnaires measured at four points throughout the study would be able to assess any primary outcomes from the initial consultation pre-treatment to follow-up post-treatment. Secondary outcomes could then be measured using MYMOP (where participants specify what the most important outcome for them is), and Hospital Anxiety and Depression Scale twice throughout the study would measure changes to mental health.

Further information

- The RCCM website has information designed for CAM practitioners interested in research, plus it runs workshops and sends updates in its CAMRN emails (www.rccm.org.uk).
- The IN CAM outcomes database can be useful for thinking about outcome measures (www.outcomesdatabase.org).
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