as other factors could have been responsible for the changes (e.g. context, age, diet etc.). It is also clear that aspects of the therapeutic context, other than hypnosis per se, will have had some affect on the outcome, e.g. the therapeutic alliance, hope, expectation, motivation of the patient and so on. For a discussion of the issues relating to evidenced-based hypnotherapy refer to Alladin, Sabatini, & Amundson (2007).

References


Background
Hypnotherapy does not lend itself easily to the currently accepted research methods of Evidence Based Medicine (EBM) which are typified by the need to test the efficacy of pharmaceutical products in isolation from other aspects of total healthcare. The gold standard of EBM research for the National Institute for Health and Clinical Excellence (NICE) and for the Medical Research Council (MRC) is the Random Controlled Trial (RCT) together with systematic reviews and meta-analysis of such trials. The ideal RCT, in terms of validity, will blind participants and deliverer to whether treatment or placebo is involved, that is, the trial is double blind. Random allocation and blinding each present particular problems in studying psychotherapeutic interventions such as hypnotherapy. In everyday practice patients for hypnotherapy are usually self-selecting and their choice of therapy may itself contribute to treatment effects in this complex intervention. This element is lost in the randomisation of participants, so although possible it may not always be desirable. Blinding hypnotherapists is not feasible as they would be aware that any placebo therapy was not hypnotherapy. Patient/participant blinding is possible but creates an ethical dilemma because in psychotherapy it is not possible to create an ‘inert’ placebo. Hypnotherapy research too often ignores these factors and research is designed to fit the prevailing EBM model. It is argued here that an expanded model of EBM is required for complex interventions, including hypnotherapy, if it is to adequately inform clinical decision making in, and affect the service availability of, complex interventions.

The clinical experience of hypnotherapy practitioners is that, for certain defined conditions, hypnotherapy provides an effective treatment. But hypnotherapy researchers working within the parameters of the current EBM model need to measure the efficacy of the hypnotic intervention in isolation. Clinicians are, by the nature of their profession, interested in the effectiveness of the entire treatment, whereas researchers are interested in isolating the efficacy of a specific primary component of the intervention. While their aspirations are not always so contrasting, this does illustrate and highlight the main differences in approach that need to be reconciled in hypnotherapy research. More often than not, the clinician and the researcher are interested in measuring different things, in different ways – each presenting different types of evidence with distinctly different types of validity. Clinicians who are also researchers, for reasons of pragmatism within the academic research environment, often adopt the ‘researcher’ approach. The clinician/researcher is often obliged to compromise one or other viewpoint to design a study that satisfies the sponsors of the research. Pragmatic clinical trials (MacPherson, 2004; Hoptof, 2002) designed to measure effectiveness of treatment in everyday practice ask different questions to those of RCTs that take place in an experimental or quasi-experimental context. Hypnotherapists and hypnotherapy researchers need to address these differences when designing research if the real value of the therapy is to be assessed.

Discussion
The double blind RCT can justifiably lay claim to being rigorous and to have a high level of internal validity but is limited in external validity. That is, when studying complex interventions it can provide evidence of the efficacy of the primary component but excludes the measurement of other facets of the complete treatment that may also contribute to effectiveness. It validates effects found in experimental or quasi-experimental conditions but it cannot tell us whether that validity is generalisable to everyday clinical practice.

There is wide acknowledgement that improved ways of evaluating complex healthcare interventions are needed. In their critique of four approaches to evaluating complex healthcare systems Boon et al. (2007) identified that the need to find ways to evaluate complex healthcare interventions, and the need to describe and understand these in context of delivery, are areas of broad agreement between MRC (Medical Research Council, UK), NCCAM (National Centre for Complementary and Alternative Medicine, USA), NAFKAM (Norwegian National Research Centre in Complementary and Alternative Medicine) and the internationally developing approach of Whole Systems Research (Ritenbaugh et al 2003; Verhoef et al 2004; 2005). The MRC, which is not primarily concerned with Complementary and Alternative Medicine (CAM), differs from the others in seeking definitive RCTs whenever this is possible (MRC, 2000). It is impossible in clinical practice to determine exactly why healing, somatic or psychological, has occurred, since there may be a range of incidental contributory intervening variables, some of which may be unidentified. The hypnotherapist’s input may be supplemented and/or hindered by concurrent physician treatment, self-help treatment, the patient’s conscious self and not least the patient’s unconscious self which can be characterised as ‘a genetically determined innate propensity to re-establish an optimum dynamic physical equilibrium’ (Fonnebe, 2007). This is equally true of mental equilibrium. These identifiable uncontrolled variables and other unidentified variables that the current EBM model postulates as the assumed constituents of the placebo effect, should as far as possible be eliminated or disregarded in research in order to establish the efficacy of the intervention being tested. Fonnebo (2007), while finding many areas of common ground between CAM practitioners and researchers, identifies the placebo as their ‘battleground’. Researchers following the EBM paradigm attempt to negate placebo effects while practitioners recognise them as conceptually central to practice – it is assumed that the ‘active’ elements of placebo may contribute to therapeutic effectiveness. The overall context of healthcare delivery is often instrumental in its effectiveness.

The question at the centre of the battleground is: are health intervention decisions best informed by measuring the efficacy of component parts of complex therapies or might the whole intervention be more effective than the sum of its parts? If the latter is the case then research should be designed to evaluate specifically that. This is what ‘pragmatic clinical trials’ (MacPherson, 2004; Hoptof, 2002) aim to do but it is RCTs that are ‘widely accepted as the most reliable method of determining the effectiveness of treatments that are to be delivered within the NHS’ (Wilson, 2005). Though true this statement is based on a false premise. RCTs are designed to assess efficacy not effectiveness – controlling all variables to assess the effect of an ‘active ingredient’ in isolation. RCTs study the efficacy of a component of the intervention, not the effect of the complete treatment.

Studying only component efficacy, comparing a treatment group that receives the component to a control group who receive a placebo, may create an ‘efficacy paradox’ [Fig.1] (Walach et al. 2006) and result in an effective treatment being discounted.

Fig.1. Hypothetical Illustration of the Efficacy Paradox, comparing two possible treatments for the same disease
(based on Walach et al. 2006)
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General Effect
Hypothetical results from two studies looking at different treatments for the same disease are shown in Figure 1. Treatment x is shown to have the largest general effect on the disease even though the difference between it and its control group is not sufficient to satisfy the parameters of statistical significance. Treatment y is less generally effective yet its difference over its control group is large enough to achieve statistical significance. Paradoxically, treatment x, the more effective for this disease, will be regarded, within the current EBM model, as having no scientific evidence to support its use. Treatment y on the other hand would be regarded as supported by scientific evidence even though it is a less effective treatment. A hypothetical example is used here to clearly illustrate the paradox.

Real comparisons are rarely made because when the statistical threshold of significance is not crossed, the results for the specific component (dependent variable) are negative and the entire study tends to be viewed likewise and therefore it is far less likely to be published due to publication bias. Publication bias works against both results that are not statistically significant and against observational studies (Easterbrook et al., 1991). A real example of the efficacy paradox is cited by Walach et al. (2006). Acupuncture was compared to conventional pharmacological intervention for the prevention of migraine and the ‘effective’ pharmacological treatment was shown not to differ from the acupuncture control (Dienner et al., 2006 in Walach et al., 2006).

Regression and artefacts should be identical for treatment and control conditions across comparative trials and therefore can be regarded as ‘white noise’, inevitable background that is not controllable. It is then clear that ‘the battleground’ is not placebo in total but only the non-specific components of treatment, some identifiable and others unknown. In hypnotherapy the identifiable non-specifics include the relationship between therapist and client, shared cultural values, client expectation and the personalisation of treatment delivery.

Non-specific components of placebo can account for treatment effects. Iphofen et al. (2005) argue that these should not be ignored, or controlled for, but studied and explained. This suggests a trial design that should study the known components of placebo as well as additional specific components of treatment, rather than regarding them as non-specific confounding variables. Such a design would be more suitable for assessing a complex intervention such as hypnotherapy because ‘factors that are incidental to biomedical encounters may be characteristic to (specific components of) psychotherapeutic ones’ (Paterson & Dieppe, 2005). However, some elements of placebo may be unknown or unidentified and these may also have treatment effects; therefore the efficacy paradox may still arise. Only measuring the effects of the whole of a complex psychotherapy, in comparison to the other available interventions, will eliminate the possibility of the efficacy paradox. Whole treatment research for a particular complaint will most effectively identify, for clinical and economic decision makers, the most effective intervention. Less effective treatments that are more costly to health service providers could be avoided, and clinicians’ and service users’ decisions will be better informed.

If hypnotherapy research is to best inform clinical decision making and service provision then it must measure the effectiveness of the whole treatment and not component efficacy alone. There is therefore a need for a research model that can be applied to hypnotherapy which provides results for whole treatments. A suitable model needs to retain the strengths of the current EBM paradigm that provides the best evidence of internal validity and expand its parameters to include evidence with high external validity.

The relevance and importance to all treatments, including hypnotherapy, of the concepts and practice of EBM are not contested here, but the weighting of evidence that has become its norm (JAMA; CEBM) requires re-evaluation. This weighting has generally been illustrated using a pyramid model such as Figure 2.

In Figure 2, research methods at the top of the pyramid have the greatest internal validity and can be subjected to more powerful statistical testing; those above the line are generally regarded as the gold standard of EBM. Below the line, the methods have decreasing levels of internal validity and are decreasingly amenable to statistical testing, yet they have increasing levels of external validity because they evidence whole treatment effectiveness in everyday clinical practice rather specific efficacy in ‘laboratory’ conditions.

Internally valid experimental and quasi-experimental RCTs, their summaries in systematic reviews (Cochrane, 2008), and the statistical combination of their results data in meta-analyses are designed to produce quantitative results with the type of control of variables that can normally be achieved only in a laboratory context. In practice many RCTs are, in fact, field trials, where control of variables is far more problematic. Despite this, many systematic reviews and meta-analyses combine results from field trials with true experiments. Once combined in this way they often become regarded as a single type of scientifically valid evidence – whether positive or negative.

Systematic reviews and meta-analyses are designed to overcome the difficulties, including those of statistical power, associated with smaller sample sizes of individual RCTs; but the variation in design of the studies (similar in topic and content) included*, may mean that the assumption of combinability of internal validity may not be as sound as it is often considered. Even if it were sound, transferability of the validity of results to the real world context of treatment delivery is an unknown and demands verification and testing if the treatment is to be adopted and continued in healthcare practice. In the same way that clinical trials of drugs have to be experimentally ‘phased’ into treating individual human beings. Case studies, case series and cohort studies can provide, either or both, qualitative and quantitative data; depending on the study design. Such studies, carried out in a real world context, will normally be openly acknowledged as field trials or will be observational studies or surveys. The studies’ context limits the extent to which incidental variables can be controlled. Even with the most careful design, the variables cannot be controlled to the same extent as they are in an experiment, therefore results will have lower internal validity - generally decreasing in line with the hierarchical model (Fig. 2). These methods do however provide important information that is unavailable in the experimental context: notably data regarding external validity. The presence of qualitative evidence sourced from healthcare practitioners and from patients; and “Evidence from qualitative studies can play an important role in adding value to systematic reviews for policy, practice and consumer decision-making” (Cochrane, 2008, chapter 20). Studies of healthcare interventions in context, that take place in normal clinical conditions, may also provide cost data for the actual delivery of treatment rather than from estimates and projections.

In relation to research methods there seems to be a prima facie tension between internal and external validity because diminished control of variables appears to threaten internal validity while optimum control for measuring component efficacy threatens external validity; and therefore a need to clearly illustrate the paradox.
Hypothetical results from two studies looking at different treatments for the same disease are shown in Figure 1. Treatment x is shown to have the largest general effect on the disease even though the difference between it and its control group is not sufficient to satisfy the parameters of statistical significance. Treatment y is less generally effective yet its difference over its control group is large enough to achieve statistical significance. Paradoxically, treatment x, the more effective for this disease, will be regarded, within the current EBM model, as having no scientific evidence to support its use. Treatment y on the other hand would be regarded as supported by scientific evidence even though it is a less effective treatment. A hypothetical example is used here to clearly illustrate the paradox. Real comparisons are rarely made because when the statistical threshold of significance is not crossed, the results for the specific component (dependent variable) are negative and the entire study tends to be viewed likewise and therefore it is far less likely to be published due to publication bias. Publication bias works against both results that are not statistically significant and against observational studies (Easterbrook et al. 1991). A real example of the efficacy paradox is cited by Walach et al. (2006). Acupuncture was compared to conventional pharmacological intervention for the prevention of migraine and the ‘effective’ pharmacological treatment was shown not to differ from the acupuncture control (Dienner et al., 2006 in Walach et al., 2006).

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In relation to research methods there seems to be a prima facie tension between internal and external validity because diminished control of variables appears to threaten internal validity while optimum control for measuring component efficacy threats external
validity. The hierarchical model (Fig.2) exacerbates this tension by over-valuing internal validity in comparison with external validity. This tension between internal and external validity is another problem that a ‘whole treatment’ research model for hypnotherapy must address. The current EBM paradigm can result in treatments becoming the practice standard, based solely on internal validity; despite the fact that healthcare is not delivered in laboratories or in clinical conditions where variables are strictly controlled in the same way. It is delivered to the ‘real world’ of human clients.

Circular models, familiar throughout the social sciences, have an academic elegance but lack a clear focus of conclusion: “A circle has no preferred orientation.” (Walach et al. 2006). Healthcare decision makers, from family doctors to governmental agencies including service users, are looking for clear and readily apparent research conclusions. While they may acknowledge that comprehensive results from a multiplicity of research methods give the best guide to effective treatment, they are unlikely to have the time and resources to study anything other than clearly presented conclusions – decision making takes place in the real world too. The hierarchical perspective, with its assumption of best evidence, presents a sharply focused conclusion at the top of the pyramid. The circular model does not match this necessary clarity of conclusion. A model that clearly focuses the conclusions, based on the integration of all available evidence, is required.

A new model for hypnotherapy research should also be applicable to other psychotherapy, to CAM research and to all EBM. There is no reason why an acceptable standard of comprehensive evidence should be different for hypnotherapy, it is one possible intervention amongst many and comparison between different treatments is essential to good decision making. Outcomes should be the measure of all healthcare research – whether the outcome measured is remission, amelioration or eradication of a disease, cost of provision or patient satisfaction. Differing philosophical approaches adopted by patients, by doctors, by psychologists, by scientists and by economists may have a place in the process of health service delivery decision making – but the research process should be as ‘detached’ and objective as possible. The biases inherent in belief systems should not influence the research methods relied upon for decision making. Whole treatment research should have hypotheses based on measurable outcomes. It is often argued that you can not compare ‘apples with oranges’ and as exemplars of different categories of fruit this is true; however, once categorised as foods, comparison of nutritional value is entirely feasible. A satisfactory healthcare research model can, by focusing on outcomes, make possible the comparison of one complex therapy with any other for the same disease.

In proposing a new model for evaluating hypnotherapy evidence it is necessary to acknowledge the power of the RCT, systematic reviews and meta-analyses. It has been proposed (Roberts, 2005) that hypnotherapy trial design should ‘allow for the incorporation of multiple methods to address all aspects of therapy’, but this would lead to a complexity of trial design that would be both a logistical nightmare and require probably unobtainable levels of funding. Furthermore it would require making compromises to one, or more, or all of the methodologies involved (a dilution or contamination of the protocols) thus compromising the power of findings from each method. It is therefore proposed here that the multiplicity of methodologies be brought together not at the trial stage, but at the review stage and that the Systematic Review (Cochrane, 2008), which is often reductionist in studying homogeneous RCTs only, should be incorporated into a new and comprehensive research review model; the Pragmatic Systematically Conducted Review (PSCR) (Fig. 3).

The model for the PSCR (Fig.3) acknowledges non-hierarchical relationships of evidence from multiple research methodologies and recognises the importance of establishing the substantive validity (Fig.4) of a treatment by confirmatory results from multiple and heterogeneous research methodologies. The PSCR model is represented by a schematic diagram from ‘logic theory’ (Venn, 1880) and while it emphasises the importance of each research methodology feeding the development of others, it also improves on the circular model (Walach et al. 2006) by presenting a clear conclusion at the ‘confluence’ where evidence from each methodology confirms and endorses that from all the others. ‘Conjunctions’ of evidence from two categories of research methods produces three secondary points of focus.

**Fig.3. Model for the Pragmatic Systematically Conducted Review (PSCR) in complex healthcare interventions such as hypnotherapy where placebo may be intrinsic in effectiveness.**

This PSCR model is pragmatic in two respects. It seeks to establish the effectiveness of a whole treatment rather than the efficacy of one active element of it, and in doing this, it takes account of both internally valid and externally valid evidence.

Validity is a central question that has divided groups with different perspectives on the usefulness of research evidence. Agencies commissioning healthcare service interventions tend to favour evidence that has very high internal validity. Clinicians, conversely, have often questioned the exclusive use of internally valid evidence for deciding on a treatment for individual patients in everyday healthcare practice (Mant, 1999; Hart, 1997).

Common sense dictates that if both the internal and external validity of a treatment have been demonstrated by research, then this
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Published papers reporting hypnotherapy studies seldom give sufficient description of the method of hypnosis. Hypnosis is primarily suggestive therapy. Suggestions given for induction of hypnosis or for the method of hypnosis. Hypnosis is becoming the practice standard, based solely on internal validity in comparison with external validity. The hierarchical perspective, with its assumption of best evidence, presents a sharply focused conclusion at the top of the pyramid. The circular model does not match this necessary clarity of conclusion. A model that clearly focuses the conclusions, based on the integration of all available evidence, is required.

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is a better indication of treatment validity than either one without the other. Furthermore, validity supported in this way is not simply the sum of the different research methods, but far greater than this. The validity of results from a category of research methodology, when the results are in agreement, substantiates the validity of those of another category; as illustrated at the conjunction intersections of the PSCR model. The confluence intersection sees the validity of each of the three categories of research methods substantiated by each of the others. The overall validity of results at any intersection is substantive and represents the best guide to the true validity of a treatment. The systematic review provides the sum of internally valid results from similar studies of a primary component of treatment. The Pragmatic Systematically Conducted Review cross-substantiates results with internal and external validity – for all studies relating to interventions, however complex, for a particular disease or condition.

Some clinicians and researchers who take a mainly relativist stance might question the fact that the model illustrated in Figure 3 does not explicitly include data from surveys and questionnaires of patient/service users/client opinion of their treatment and their judgement of its effectiveness. Whether or not that should be included is one of the most contentious issues and there is not room to explore it in detail here. The PSCR model can easily be expanded to include this as a fourth category, indeed there is theoretically no limit to the number of categories that can be used, but there is a practical one. The greater the number of categories, the less concise the conclusions will be. The concept of this PSCR model is the use of three broad but distinct categories of healthcare research methodology to present a clearly focused confluence of substantively valid evidence. A multiplicity of narrower categories would defeat this object by obscuring the focus.

The PSCR will only fulfil its aims if the protocol adopted for its conduct is rigorous and measures are included to eliminate researcher bias. That is, every stage of the review must be conducted systematically while being comprehensive in its scope. It must seek to establish substantive validity by studying outcomes in isolation from the theories underlying the research methods of individual studies, but without dismissing the context in which the studies were conducted.

To lay claim to substantiating the results of diverse research methodologies in studying a healthcare intervention for a particular disease or condition, a systematic and exhaustive approach to searching for studies to be included in a PSCR is required and every effort to include every possible source of evidence is essential.

Results from any research methodology are only included in the substantive results (Figure 3. intersections f) when the studies are in agreement. Evidence from any category of research methodology that is not substantiated by evidence from another is not included. The optimally substantive focus of the results (Figure 3. intersection f) only includes results that are in agreement with both other categories. This differentiates the PSCR from triangulation methods that compare and attempt to interpret results whether they agree or conflict.

Some publications covering hypnosis and hypnotherapy research span many disciplines including medicine, psychology, psychotherapy, nursing and CAM. Electronic databases for all these fields must be searched systematically using relevant search parameters and all results recorded. Unfortunately what was the only substantial specialist hypnosis research database is no longer on-line, reportedly due to loss of sponsorship.

Recorded search results will need to be included or excluded from the PSCR according to precise criteria rather than by arbitrary or biased judgement. All papers that meet the criteria must be included. Parameters for data extraction, whether quantitative or qualitative, will also need to be precisely stated and adhered to.

Four categories of results will be presented – the primary results of the confluence (f Fig.3) and three sets of secondary results of the conjunctions (ab;ac;bc; Fig3).

A hierarchical perspective on differing methodologies can remain relevant within the PSCR. It may for instance be reasonable to weight the evidence of conjunction ab (Fig.3) above that of ac and that of bc. Whatever the favoured perspective of the decision maker, the evidence at each intersection will provide more information on overall validity than a single ‘definitive’ evidence base. The central intersection f (Fig3) will always focus the substantiated evidence of optimal validity.

Synthesis of heterogeneous research methods to provide internal and external validity of results without loss of integrity is difficult, if not impossible, within individual studies. A review of studies on the other hand represents an opportunity to synthesise results from diverse methodologies without compromising the integrity of any one of them. Furthermore, because results in agreement from differing methodologies cross-substantiate internal and external validity, the overall integrity of total research is improved to provide substantive validity of results.

The Pragmatic Systematically Conducted Review is proposed here as a suitable research review model for the synthesis of quantitative and qualitative evidence of internal validity and external validity for complex healthcare interventions. The model is capable of delivering comprehensive substantively valid evidence in a concise and focused summary to aid the facilitation of clinical and economic decision making in healthcare provision.

Conclusions
is a better indication of treatment validity than either one without the other. Furthermore, validity supported in this way is not simply the sum of the different research methods, but far greater than this. The validity of results from a category of research methodology, when the results are in agreement, substantiates the validity of those of another category; as illustrated at the conjunction intersections of the PSCR model. The confluence intersection sees the validity of each of the three categories of research methods substantiated by each of the others. The overall validity of results at any intersection is substantive and represents the best guide to the true validity of a treatment. The systematic review provides the sum of internally valid results from similar studies of a primary component of treatment. The Pragmatic Systematically Conducted Review cross-substantiates results with internal and external validity – for all studies relating to interventions, however complex, for a particular disease or condition.

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Some clinicians and researchers who take a mainly relativistic stance might question the fact that the model illustrated in Figure 3 does not explicitly include data from surveys and questionnaires of patient/service user/client opinion of their treatment and their judgement of its effectiveness. Whether or not that should be included is one of the most contentious issues and there is no room to explore it in detail here. The PSCR model can easily be expanded to include this as a fourth category, indeed there is theoretically no limit to the number of categories that can be used, but there is a practical one. The greater the number of categories, the less concise the conclusions will be. The concept of this PSCR model is the use of three broad but distinct categories of healthcare research methodology to present a clearly focused confluence of substantively valid evidence. A multiplicity of narrower categories would defeat this object by obscuring the focus.

Results from any research methodology are only included in the substantive results (Figure 3. intersections f focus = intersection abc); ab; ac; bc) when they are in agreement. Evidence from any category of research methodology that is not substantiated by evidence from another is not included. The optimally substantive focus of the results (Figure 3. intersection f) only includes results that are in agreement with both other categories. This differentiates the PSCR from triangulation methods that compare and attempt to interpret results whether they agree or conflict.

Conclusions

In order to provide the best possible evidence to decision makers including service providers, clinicians and patients, there is a need to improve hypnotherapy research design to study whole treatment effectiveness in terms of outcomes and validity of results. Reliance on one ‘definitive’ research methodology that measures only the efficacy of a primary component of a complex intervention is unsatisfactory because it provides only evidence of internal validity; because it does not test all facets of the treatment an efficacy paradox may result. External validity of whole treatments can only be studied in the context of everyday service delivery. Results from field research methods need to be synthesised with experimental evidence for internal and external validation in order to establish substantive validity of a complex healthcare intervention such as hypnotherapy.

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The PSCR will only fulfil its aims if the protocol adopted for its conduct is rigorous and measures are included to eliminate researcher bias. That is, every stage of the review must be conducted systematically while being comprehensive in its scope. It must seek to establish substantive validity by studying outcomes in isolation from the theories underlying the research methods of individual studies, but without dismissing the context in which the studies were conducted.

To lay claim to substantiating the results of diverse research methodologies in studying a healthcare intervention for a particular disease or condition, a systematic and exhaustive approach to searching for studies to be included in a PSCR is required and every effort to include every possible source of evidence is essential.

A hierarchical perspective on differing methodologies can remain relevant within the PSCR. It may for instance be reasonable to weight the evidence of conjunction ab (Fig.3) above that of ac and or that of bc. Whatever the favoured perspective of the decision maker, the evidence at each intersection will provide more information on overall validity than a single ‘definitive’ evidence base. The central intersection f (Fig.3) will always focus the substantiated evidence of optimal validity.

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Intrapersonal Communication: the Hidden Language

(Part 1 of a series 5)

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Abstract:
This article is the first in a series of five which seeks to site scientific psycho-hypnotherapy on a firm linguistico-philosophical foundation. We find that for consciousness, both “hardware” (the brain’s prefrontal cortex) and “software” (psychological mechanisms such as imagery and inner speech, as well as the content of self-reflection), are necessary. Crucially, it is found that part of the filtering process which takes place in the transfer of information from the external world to the internal or psychic world via the sensory channels, renders the information in the form of language, and this leads to the establishing of a “self-talk.” We find that in terms of the “psychological software” for self-awareness, internal dialogue is immensely important. We then go on to summarise the scientific background to our understanding of the nature and prevalence of self-talk and its relationship to self-awareness, in terms of meaning-making and shaping reality, both private and consensual. At this point we turn to Wittgenstein who believed that “philosophico-linguistic therapy” could be at the heart of clearing up many of life’s conundrums, and we sketch out, in practical terms, how such therapy might be applied to facilitate creative psychic change and personal development. We aim, at the conclusion of these discussions, to show how a “therapy for self-talk,” as engendered in the tools and techniques of Neuro-linguistic Programming and Psycho-chaotic Semiotics can produce apparently “magical” results in the creation of unfolding, positive realities of choice.

Keywords:

References
2. CEBM ‘Levels of Evidence’, Centre for Evidence Based Medicine, Oxford; available at http://www.cebm.net/index.aspx?o=1025
14. Paterson, C., and Dieppe, P. 2005 ‘Characteristic and incidental (placebo) effects in complex interventions such as acupuncture’ British Medical Journal, 330, pp.228-230