Conducting research in herbal and complementary medicine

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This paper outlines information and advice on how a practitioner can formally pursue research pertaining to herbal or complementary medicine. It recommends five practical steps: get advice and acquire skills, find out what other people have done already, consider what research you want to do, decide on a design and finalise a detailed research plan. Enrolling in a postgraduate research degree program is recommended as a way to acquire basic research skills and obtain support for an initial project.

Key words: Research methods; herbal medicine; complementary medicine

Introduction

Many health practitioners have at some time contemplated the idea of undertaking research. The thought may remain a passing desire to investigate a question or may develop into a passion to undertake research. Herbal medicine (HM) and complementary medicine (CM) research is still in its infancy in Australia and some practitioners may lack confidence in converting their curiosity or interest. The current paper offers suggestions on where and how to get started. It suggests five initial steps: get advice and acquire skills, find out what other people have done already, consider what research you want to do, decide on a design and finalise a detailed research plan.

The paper particularly focuses on obtaining research training and on studies that involve human or animal participants. It is important to recognise that other legitimate research foci, e.g. a study of historical developments, philosophy of science or sociocultural study, may require different methodologies than are described here.

1. Get advice and acquire skills

Starting a research project is very challenging if a practitioner does not have research training and experience. There are traps for the unwary and it is wise to begin by collaborating with experienced researchers. This not only helps practitioners to complete a high quality project, it also provides skills they can take to future research.

If the practitioner can find an established researcher who shares their ideas and would like to collaborate, this may provide sufficient support. However if the project is not a central priority for the collaborator it may be difficult to ensure that long term support is obtained. There is a better chance of ensuring other demands do not take priority if a collaborator is a supervisor in a tertiary program since this produces an obligation to provide satisfactory support to a project's completion. The obligation is underpinned by institutional procedures that help ensure that this occurs.

Professional training programs often include a research component and that may be sufficient to meet the needs of many practitioners who wish to do research but do not plan a research career. However the best way to obtain a coherent and substantial program of research training is to undertake a postgraduate research degree. These programs offer sustained support, systematic research training and practical resources (internet, library, laboratory, office and equipment access, and usually financial assistance). Satisfactory completion of a postgraduate program provides credibility as a researcher, potentially opening additional career options and enhancing ability to obtain research funding.

The vision of completing a substantial research project and thesis can be daunting to prospective researchers. However projects can be broken into achievable sub-tasks that progressively build skills. These sub-tasks progress from a brief description of initial ideas, refinement of a literature review and research proposal and detailed planning, to the conduct, analysis and write up of one or more projects. An increasingly popular way to break tasks into discrete units that offer clear deadlines and sequential achievements is to divide a postgraduate program into a set of peer reviewed journal papers. There are many advantages in this approach. The discipline of a strict maximum word length for an article keeps reviews and research descriptions succinct and gives valuable experience in research writing. Progressive publications ensure that the researcher has an early impact on the field and a series of well received papers opens additional opportunities (e.g. scholarships or travel grants and subsequent employment or research funding). Detailed feedback from reviewers alerts the researcher to limitations, often in time for modifications to projects or their write up. In essence, reviewers supplement the advisory team offering independent advice. Acceptance of papers in peer reviewed journals also makes it difficult for subsequent markers to criticise the thesis severely, especially if the journals have a high profile. Publications also provide concrete rewards for the advisory team. In many universities, candidates can even choose to submit a set of papers (usually with the addition of an introduction and a commentary) in place of a traditional thesis.

Fulfilling criteria to enter a postgraduate research program

Some universities allow direct entry to a postgraduate research program with a pass undergraduate degree plus practice experience. However most require applicants for Doctor of Philosophy (PhD) programs to have a strong undergraduate honours degree (e.g. Honours I or IIA/II-1) or its equivalent (e.g. a Masters degree). That program must usually include a substantial research project. Since universities differ in their entry requirements, it is important to consult websites of universities under consideration.

Even if a university requires more research experience for entry, applicants with a pass degree and strong grades may be able to enter a PhD program after completing a one year honours qualification. If an applicant holds an honours or Masters qualification that does not quite meet requirements for direct PhD entry (e.g. an insufficient research component or an insufficient grade of honours), entry to a Master in Philosophy (MPhil) program may be an option. Provided progress targets are met, universities typically provide for a subsequent application to transfer to the doctoral program. This pathway has the advantage of requiring a shorter period of initial commitment and it does not necessarily extend the overall time to attain a doctorate, since research before transferring to a PhD can be counted.

Choosing a university

Any university is a potential option since all have potential supervisors for most projects. However there are advantages in finding a university with research groups that have similar interests to your own. Currently in Australia, CM research groups are at Southern Cross University, the Universities of New England, Western Sydney, Queensland and Sydney, and at RMIT. The research expertise of a university need not be specifically in herbal medicine. It may be in a specific research technique or area of research. Universities, schools and research centres all have areas of particular strength or priority. A particularly strong and successful research group may not always be the best current fit to the early researcher's needs, for example the student can sometimes have fierce competition for advisor time.

Choice of a research context should also include ready access to library or other resources, required equipment or laboratory facilities, and an available research population.

Another important criterion in choosing a university is access. The researcher needs ready access to the advisory team and resources, which is enhanced by a shorter distance from the home or workplace. The university may allow students to undertake postgraduate research at a distance, and a combination of electronic communication and face to face visits can support some projects. Distance does magnify logistical challenges, and there are minimum requirements for on site study over the program.

Most students find that on site location is particularly helpful when planning research, submitting a proposal, undertaking statistical analyses and finalising their thesis.

Selecting an advisory team

Engaging an effective advisory team is critical when starting research, regardless of whether it involves postgraduate study. Advisors as a group must have the skills and commitment to you and your project to provide optimal assistance. If the research closely matches the specific interests and skills of at least one advisor, you can have greater confidence that they will share your enthusiasm, be aware of developments in the field and help you maximise the quality and impact of your project.

If you enrol for a research degree, the primary advisor must have an honorary or substantive post in the university you are enrolling in and hold at least the qualification level they are supervising. Since there is a paucity of HM or CM academics with doctoral degrees, it may be challenging to find people from those fields who fulfil this requirement. Associate advisors can typically be appointed on practice skills alone, and in some cases a team may need to be from more than one university. The university will require at least one advisor who has an employment contract that extends as long as your expected candidature, so you can be assured of supervision continuity.

A good supervisor must not only have relevant interests and skills, but must also be able to work with the student. In a doctoral degree this will be a long term partnership. An effective relationship and generic skills in supervision can be more important than obtaining a perfect match of interests. Supervisors vary in skills as educators, supervision styles and even commitment. Some are more demanding, some more empathic and some are better at meeting particular needs (e.g. literature review, project management, statistical analysis, writing or developing independence). Some supervisors are more effective at particular stages of the program. You both need to decide whether there is a close enough match for both needs. You may find it useful to talk to previous supervisees, while appreciating that their experience might not be the same as your own. You will need to become comfortable with this person, to feel safe to talk about research problems and admit to ignorance and perceived mistakes, if you are to gain the most benefit from the relationship. If problems do develop in the relationship, universities have staff who can help resolve the issues and if necessary change your advisory team.

In many cases specific needs emerge during research which are optimally addressed by people outside the advisory team. You may attend training at other places (e.g. on specific techniques), briefly visit other researchers or ask questions by phone or email. These contacts not only enrich your training, they can also prove useful in finding sympathetic markers and identifying potential referees for employment applications.

How to apply for entry

Enrolment in a research degree typically requires only the completion of enrolment and research proposal forms. Forms and procedures vary between universities but you may be asked to outline reasons for undertaking the program, describe a research question, outline current relevant literature and a proposed project, identify likely resource requirements and set a time frame for completion. Typically you are asked only for a few paragraphs on each issue, and these are tentative responses. It is understood that projects often change dramatically over subsequent months.

A Master of Philosophy requires at least 12 months of full time enrolment but usually takes 18-24 months depending on topic and progress. A PhD typically requires at least 3 years of full time enrolment with most people needing 3.5 to 4 years. Universities vary in maximum lengths of candidature but all strongly encourage completion of a Masters degree within 2 years and a PhD within 4 years. In Australia postgraduate research programs are exempt from fees, and tax free scholarships are available on a competitive basis. In other countries fees are usually payable but in some cases a scholarship to waive fees or offer a stipend may be available.

Part time enrolment may be the only viable option for many practitioners. The upside is that this is likely to provide more income during the research program. The downside is that it extends completion times and poses challenges in maintaining motivation and the project's novelty. If the research idea has commercial potential, patents may be taken by others if preparatory studies are delayed. Part time enrolment also poses challenges for time management and places higher demands on recreational time and on the family. Successful part time study requires that employment hours and duties are compatible with requirements of the research. One way to accomplish compatibility is to undertake a project that fits into priorities of the workplace and that uses its facilities or clients.

2. Find out what other people have done already

The fact that someone else may have already looked at your area of interest may not matter. Often your question is not the same as theirs or on careful reading you notice ways you could answer the question more effectively. However it is important to know where other researchers have reached and identify minimum standards and accepted procedures for research in the area.

While an internet search can be a rich source of information, it is difficult to judge its quality and much will be missed if that is the only source. Peer reviewed journals offer an assurance of quality, and library search engines (e.g. Medline) offer a powerful method to locate publications. Not all HM journals are listed in these databases and even the most careful search can miss a key paper. Located papers are supplemented by a careful review of their reference lists.

As an initial strategy carefully read recent reviews of the area - these provide an orientation to current questions and methodology. You will need to develop your own view of the issues rather than rely on insights of others. Reviews reflect both strengths and the weaknesses of current ideas and major advances often require a fresh look at the issues and evidence. Reviewers may miss or misinterpret papers and their conclusions will not always mirror your own.

It is a good idea to write down initial ideas to help structure early discussions with your advisor. These notes should not only summarise the papers you read, but also include ideas about questions or potential research studies and outline arguments about key issues. At first they may be random dot points, but as ideas develop a more formal review of the area should be undertaken. You may consider publishing this review (or parts of it) to stake your claim as a prospective contributor to the field. If you are undertaking a research degree a review is required for confirmation of candidature and acceptance of the research prospectus. It also constitutes a draft of the thesis introduction.

3. Consider what research you want to do

There are three key questions to ask when choosing a research question and developing a preliminary plan.

(a) Are you enthusiastic about the idea?

Whether the research is part of a tertiary program or not, it will last some time and has costs attached (e.g. time, opportunities, financial). At some points you will probably be frustrated by it or will wish it were over. Your excitement and curiosity about the idea must be enough to sustain you through these periods.

(b) Will this research make a difference?

Is the idea novel? Is the problem that it addresses an important one? Will this research provide a substantial contribution to our understanding of the problem, or to clinical practice? Are there ways the idea could be modified to increase its impact? What would happen if this research were never done?

Enthusiasm for an idea can blind researchers to its arcane or even trivial nature. The views of others provide a more objective assessment of significance. While innovations in theory and practice are sometimes undervalued by others who are committed to existing notions, a consensus that a project has low potential impact is usually correct. At least one advisor should share your faith in your project's significance.

(c) Is it feasible?

Can the project be completed in the available time? Does the research team have the skills to complete it or access to ways of developing those skills? Can you obtain required participants? Can you access equipment, space or other resources to complete it?

A critical criterion is how a high quality piece of work can be finished within the required time frame with minimal pain. As an idea develops it often becomes too complicated or ambitious and needs to be scaled back. Rigorous analysis of each element is needed. It is important to remember that a university program provides training for research rather than constituting your life's work.

Feasibility (and advisor enthusiasm) can be enhanced by undertaking a project that interfaces closely with other research by an advisor. When considering this as an option you need to ensure that you will be able to 'own' a clearly defined and agreed aspect as your own (e.g. for your thesis and for publication or patent). If there are several investigators on their advisor's project, it is important to ensure that all investigators agree to the division of intellectual property. A further consideration is that you need to be sure that there

are no potential problems in the associated project that would put your own at risk.

4. Decide on a design

Different designs answer different questions about the area of interest. Each has strengths but also has limitations and implications for feasibility. Consideration of designs helps to refine the research question further.

Basic laboratory research

Basic research may be descriptive (e.g. a chemical analysis of different herbal preparations), but more typically involves manipulating a variable of interest while keeping other aspects constant (e.g. observing in vitro reactions of an HM constituent in a control and experimental cell line). Laboratory based research allows substantial experimental control but typically requires well developed skills in using specialised equipment and procedures. This sometimes requires completion of a preliminary course or may involve on site training by a technician.

Cross sectional studies

These studies examine responses at one point in time (e.g. community attitudes to natural therapies or research on current practices). Often these involve examining characteristics associated with particular behaviours, attitudes or treatment outcomes. Such studies are usually easier to conduct than ones that follow the same people through time. It is hard to determine causal relationships if there is only one occasion of measurement and no attempt at experimental manipulation. An association between positive attitudes to herbal medicine and its impact might be because respondents were pleased with its effect, or positive health outcomes may be due to the attitude (e.g. a placebo response), or both may be due to a third factor (e.g. greater commitment to health maintenance).

Longitudinal studies

Longitudinal studies repeatedly assess the same sample over time, e.g. examining outcomes of treatments. Longitudinal designs allow researchers to disentangle directions of influence. If participants had positive attitudes to HM before receiving it and these attitudes did not subsequently change, the attitudes were not caused by the HM. These designs also allow researchers to measure and partial out effects of confounding variables.

A longer duration of follow up provides greater confidence that effects are maintained, but also delays completion of the project and minimising dropouts can be challenging. If lost participants are not included the study's results can be misleading (e.g. if results of a trial only included people who stayed in a study because it was effective, the study would overestimate its effectiveness). While statistical procedures can deal with dropouts (and dropout can itself be an outcome), lost data is ambiguous (e.g. participants may not return because they have recovered or because they are not receiving benefit) and estimations are at best an intelligent guess. It is important to find ways to retain participants (e.g. requesting multiple contact methods or providing incentives).

A simple predictive study can be highly compatible with routine clinical practice. Requirements include a standard assessment protocol, information about treatment and high follow up rates. Responses to treatment may be predicted from initial assessments conducted or from measures during treatment (e.g. adherence).

Treatment outcome trials

A subset of longitudinal designs involves comparing treatments. At its simplest level this comprises a study of outcomes on one or more uncontrolled case or a program evaluation. The latter is essentially a predictive study on a specific program. A limitation of uncontrolled case studies is that they cannot directly test whether participants would have recovered anyway, or whether effects differ from alternative treatments.

A quasi-experimental design gives different treatments to subsets of participants without random assignment. Some may wait for a treatment or receive standard care, however the lack of random assignment means that differential outcomes may be due to pre-existing characteristics.

A type of quasi-experimental design that offers greater confidence in results involves 'single case' or 'N = 1' methodology. These designs study one case or a small number of cases in detail and retain flexibility in the delivery and refinement of

treatment during the study. They all require repeated (if not continuous) assessment including one or more baseline or control period, and need stability in the dependent measure. An example is an ABA, Return-to-Baseline or Reversal design, where a control intervention (A) is alternated with an experimental intervention (B). If on return to the control intervention a measure (e.g. side effect level) returns to its original level, the researcher can have confidence that a change from the active intervention was not simply due to elapsed time. More than one reversal of the conditions (e.g. ABAB) gives more faith in the attribution of effects to the experimental condition, rather than for example coincidental change in other factors. An example could involve testing hawthorn (*Crataegus oxycantha*) extract vs. placebo in people with high blood pressure. Blood pressure would be tested repeatedly through the study. Responses to successive periods of placebo and hawthorn extract could be examined. Versions of this design involve more than one active treatment (e.g. ABAC or ABCBC where C is an additional active treatment).

An ABA design relies on a clear cut response emerging during the treatment phase and at least partial reversion to previous status during the repeated baseline. If the treatment has lasting effects (e.g. sustained recovery occurs), ABA effectively becomes an uncontrolled case study. It may be ethically inappropriate to withdraw treatment to see a replicated effect (e.g. where a problem is potentially life threatening).

Another single case design has multiple baselines where a treatment is progressively given to different individuals, or in different contexts, and controls continue to receive a baseline until it is their turn to receive treatment. A wait list design is like a multiple baseline applied to two randomly allocated groups where one group waits before it receives the experimental treatment. In the single case version, two or more individuals progressively obtain the treatment. A requirement is that treatment of one person (or treatment in one setting) does not affect the remainder. This can be difficult with some treatments (e.g. where meditation is the CM, a patient may talk about the skill with another who is waiting). Since the baseline of the last person or context continues until all previous ones receive treatment, this can involve an extensive baseline if there are many people or contexts. There are many other single case designs and combinations are possible (e.g. multiple baseline plus ABA).

Randomised controlled trials (RCTs) allocate participants into groups using random numbers or permutations, sometimes controlling for particular characteristics (e.g. gender). With sufficient numbers, randomisation makes it likely that conditions will be roughly matched on potentially confounding characteristics, although this matching cannot be guaranteed especially in studies with small to medium size (e.g. ≤ 50 participants).

For the development of medicines research is conventionally divided into phases. Phase I trials involve preliminary tests of safety and side effect profiles, physiological responses and appropriate doses in a small sample who are examined intensively. Phase II trials examine the feasibility of a treatment outcome trial testing beneficial and negative effects of the medicine and refining information about effective doses. Phase I and II trials are typically multiple case studies or quasi-experiments although some Phase II trials may have a small scale randomised design (offering a short term pilot for a Phase III trial). Phase III trials are usually large scale RCTs on the new treatment, comparing it with control interventions (e.g. a current standard treatment). Phase IV trials examine effects and risks of the treatment in routine practice. While the phases were identified primarily with synthetic medicines in mind, they are equally applicable to HM.

An additive design can be used to test combinations of interventions. An advantage of this approach is that a combination of interventions better reflects CM practice. It is also possible to determine whether combinations of interventions (e.g. HMs) are more effective than a monotherapy. An example of a 4 week RCT exploring HM in the treatment of insomnia could involve participants being randomised to placebo, valerian (*Valeriana off.*), or to valerian plus hops (*Humulus lupulus*). The trial may even have a fourth group receiving an individualised herbal formula. Significant methodological and logistical challenges may be encountered. Since differences between effects of active treatments may be small, large numbers of patients may be required to obtain a statistically significant difference between those interventions. This is costly and requires more resources and time than a comparison with placebo or wait list conditions (where differences in effect are typically larger). In the above case if numbers were insufficient, active treatments may show superior effects to placebo, but no significant differences between them may be observed.

Whole systems research

RCTs on a single treatment or constituent are commonly regarded by the orthodox medical community as the 'gold standard' measure to determine evidence of efficacy (Pirotta 2007). Many caveats exist when applying a reductive model to determine efficacy of CM. Practitioners of phytotherapy and CM use individualised prescriptions to treat the "whole" person (mind-body and interconnected systems). This holistic practice cannot be adequately explored via trials that reduce the intervention to a single mono-therapy or isolated constituent. While complex or multicomponent therapies (e.g. Maizels 2004) and global subjective measures of quality of life or similar concepts are commonly evaluated in RCTs, these designs still typically apply standard protocols across individuals and look for average effects.

The construct of 'whole systems research' has been developed to meet the shortcomings of reductive research and better test and understand practice of CM (Ritenbaugh 2003).

This individualised approach can be applied within controlled designs (including N = 1 designs), but more often use naturalistic, multiple case studies. These studies are subject to all the limitations of uncontrolled case studies that were identified above (e.g. confounding with natural recovery and placebo effects) and they cannot identify which aspects of a complex intervention were responsible for an effect or how they worked. If conducted by a single practitioner these studies are also confounded with practitioner skill or other individual characteristics. However a substantial body of case studies from multiple treatment centres provides robust preliminary support for a particular practice.

A middle ground between a phased approach to refinement of interventions and a whole systems approach can be found. For example decision rules about individual tailoring of treatments can be formulated and progressively refined during a study so that the process of individualisation can be reported and potentially replicated by others.

Questions about specific contributions of components, including the decision rules and the presence of individualisation, can then be progressively tested within standard controlled trials.

Qualitative methodology

Qualitative approaches to research provide an opportunity to derive rich, detailed information about individual experience and are particularly useful where little is known about the phenomenon or where a focused quantitative approach may miss critical issues. For example views of doctors about CM or HM might be canvassed (e.g. Miha 2007) or decision making about CM examined (e.g. Caspi 2002).

Qualitative approaches all tend to ask individuals or focus groups a set of open ended questions and then derive categories or themes from the transcripts. Many use a grounded theory approach (Glaser 1967). Commonly independent raters look for categories or themes from the responses, followed by a process of checking for consistency (sometimes including a statistical report of inter-rater reliability). Further transcripts are obtained and reviewed until no new themes emerge (redundancy is reached). Higher order categories may then be derived (usually by consensus between raters). Studies with higher research quality may have fidelity raters to confirm the categories, ask the respondents whether categories and themes accurately reflect their views and examine whether rater biases affected the results. Reports of qualitative studies typically report both the themes and quotations (exemplars) to clarify their meaning. Derivation of themes may be undertaken by hand, or be assisted by software such as NUD*IST© (Richards 2002, now superseded by NVIVO$_7$©), which help record categories and their hierarchies.

Researchers considering qualitative measurement should remember that the formulation of questions and collection of data can be relatively easy, but derivation of themes can be extremely time consuming. For this reason the number of questions should be kept to a minimum. Since closed questions can affect open ended responses, where researchers want to use a combination of questionnaires and qualitative analyses, closed questions on a similar topic should be administered after a qualitative measure.

Qualitative methods are excellent for development of hypotheses and for understanding phenomen-ological experience or examining salient attitudes or beliefs. Impressions of the importance or frequency of themes can be obtained within these approaches but the methodology is not intended to provide quantitative data. Subsequent research with focused, quantitative methods (e.g. giving the same

closed question to all participants) is advised for the measurement of frequency or intensity (e.g. of a side effect or reason for HM use).

Mixed methodology research

To better assess efficacy and treatment outcomes, controlled mixed method designs can be implemented using a combination of qualitative and quantitative assessments (Verhoef 2007). The strength of combining these methodological approaches includes the ability to assess efficacy (quantitative) as well as exploring the healing experience (qualitative). Augmentation of an RCT with qualitative assessment also explores areas that may not yet be uncovered. For example an RCT could involve testing over 4 weeks the hypnotic effect of valerian against placebo in subjects with insomnia. Quantitative measures may include sleep latency and hours slept. Qualitative assessment may involve a semi-structured interview asking questions such as 'What has been your personal experience of taking the tablets?'. Responses may identify as yet undetected benefits or side effects. These phenomena could be used to derive hypotheses for further test in a subsequent study.

The importance of qualitative data is highlighted by the fact that researchers' preconceptions often retard the development of medical advances - the delay in acceptance of *Heliobactor pylori* is an example (Kavanagh 2007). Many significant advances in orthodox pharmaceuticals, including lithium carbonate and Viagra©, were the result of serendipitous patient reports (Kavanagh 2007).

5. Finalise a detailed research plan

Obtain access to resources

Access to space and to financial or other resources should be obtained early in the planning process and formal approval and scheduling must be in place before the research schedule is finalised. Potential threats to resources need to be considered (e.g. not receiving a scholarship, equipment being updated or recalibrated, competing clinical demands or competing projects) and contingency plans need to be put in place for significant risks.

Choose measures

A review of potential assessment measures should ensure that they are reliable, valid and (in a longitudinal study) sensitive to change. They should reach international standards and be readily accepted by high quality journals in the area. You should ensure the assessment measures are readily available, any required training in using these can be accessed and their cost is within budget. For a treatment trial a ready supply of the intervention e.g. herb/s or nutrient/s (and if applicable placebo) needs to be identified. You may have to wait for project approval by relevant institutions and ethics committees before equipment, measures or medicines are obtained and delivery times can be extensive, especially if items are sourced from overseas or require special production (e.g. placebos matching the HM in appearance).

Determine the required sample

In research involving human or animal participants, the sample of participants should be representative of the population you wish to study. While it is tempting to limit criteria for inclusion to ensure a relatively homogeneous sample, greater restrictions can pose problems for recruitment and limits the ability to generalise to a general population (e.g. regular clinic attendees).

Representativeness and confidence in a study's conclusions are influenced by the number of participants in a study. This number depends on the study's design, whether measures are continuous or categorical (e.g. improved/not improved) and how large an effect is expected. There are readily available computer programs that can help you calculate sample size, some of which are free (e.g. GPower, www.psycho.uni-duesseldorf.de/abteilungen/aap/gpower3/).

If you do not have training in experimental design and analysis, it may be wise to seek statistical advice before deciding on sample size. Three concepts are required to calculate and interpret power analyses. Alpha (α) is the chance that there is really no difference between the averages, proportions or correlations you may obtain. The standard maximum is .05, i.e. we tolerate making this error no more than 5% of the time. Power is the chance that we will detect a true effect with this sample size - here the standard minimum is .80 (i.e. we want to detect a true effect at least 80% of the time). You may sometimes see power expressed as $1-\beta$ (beta is the risk of missing a true effect). The third concept is effect size. This is the size of the minimum difference you want to be able to detect. For a test of a difference between two averages, this

may be expressed in standard deviation units which adjust for the degree of spread around different averages. Required sample sizes increase dramatically as effect sizes decrease. For example for two groups studied on one occasion, 14 participants are needed in each group to detect 1 standard deviation difference between averages, with $\alpha = .05$ and Power = .80. However 51 are needed in each group if you want to detect a half standard deviation difference. Differences in effects between two active treatments (e.g. as in the previous valerian vs. valerian plus hops example) are often less pronounced and hence larger sample sizes are required.

Finalise plans to obtain participants

How easy it is to recruit human participants will depend on the number who fulfil inclusion criteria in the potential catchment area, ease of accessing them and the project's attractiveness (e.g. potential treatment benefits or other incentives). Recruiting people for a project involves similar marketing skills that practitioners use to attract clients to their business. In clinical trials one strategy is to engage potential referral agents such as clinics. The research should interface with the interests and strategic priorities of the referral agency, for example it should not reduce the earnings of a private practice by taking away patients. Rather it should fill an unmet need or provide a competitive edge.

As with individual participants, agencies are more likely to participate if the project involves low cost (e.g. minimal staff time and inconvenience) and provides significant perceived benefit. Discussions with the practice manager and key practitioners may reassure them that these criteria are satisfied. Permission can then be sought to send posters, flyers or referral letters. In some circumstances the clinic may agree to researchers screening consenting patients or contacting practitioners at regular intervals to ask about potential referrals.

Direct marketing to potential participants may be undertaken through electronic and print media, provided that community volunteers are suitable for the study. While recruitment cannot begin until ethical clearances are obtained, preliminary plans for marketing, including timing of media campaigns and preparation of draft press releases can be undertaken earlier.

Obtain ethical clearances

When conducting research that involves humans or animals, an ethics proposal needs to be submitted to be considered a recognised committee of the institution where the research will be sited. Ethical review confirms that risks of harm, discomfort and inconvenience are minimised and expected benefits are sufficient to compensate for any negative effects that might occur. In Australia ethical guidelines can be accessed from the National Health and Medical Research Council website (www.nhmrc.gov.au). Human ethical guidelines have recently been revised (NHMRC 2007).

If a project is across more than one institution, it must be considered by all committees unless there is an overarching committee for multiple sites. Committees may have separate forms for completion although attempts are being made to standardise formats. If the research is being conducted in a health facility, but is part of a university program, a university committee typically considers it after approval by the relevant health service committee. Approval can take as little as a week after submission (in the case of some uncomplicated projects, especially with prior approval by another committee), or can stretch over several months. It is wise to submit proposals at the earliest possible stage to avoid delay.

While key foci for an ethics committee are the risks and participant rights, a consideration of benefits may involve a subcommittee examining the methodology and feasibility of the research to ensure that benefits are likely. Ethical approval in a health service may also require assurance of approved service access. It is therefore wise to gain in principle support for the project from a managerial gatekeeper before submitting the proposal.

Develop a list of tasks and a schedule for completion

Treat the research project like a building construction. Identify the major tasks, who will do them and how long they will take, and create a graphical schedule. Allow for unforeseen delays and avoid ambitious estimates of time frames. While the schedule will need to be modified as the project progresses, creating it will highlight potential problems and periods where greater time investment will be needed.

Conclusion

With good advice and with careful planning and preparation, getting started on a research project can readily be broken into small, achievable steps. Converting initial curiosity into action is an exciting venture. We hope that many readers of this paper will catch the excitement and take the plunge.

Further reading

University study: Details on how to make the most of supervision and successfully complete postgraduate research can be obtained on many university websites.

Single case designs: For details on how to choose and conduct this type of study consult a relevant text (e.g. Kratochwill 1992).

Quantitative research design: Hart (2003) provides a brief paper on the challenges of determining a question and design for a herbal medicine trial.

Qualitative research: A brief review of qualitative methods in psychology is given by Silverstein, Auerbach and Levant (2006). Texts include Patton (2002), and Strauss & Corbin (1990).

Mixed method designs: See reviews such as Verhoef, Casebeer & Hilsden (2002).

Research in CAM (Adams 2007): Leading researchers provide excellent insight into various forms of research as they apply to CAM.

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