

20 Research

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Medical diseases and psychiatric disorders come together more frequently in older people. These conditions interact with each other, and with environmental and psychological variables to produce characteristic problems for management and treatment. This poses particular challenges for research. Old age psychiatrists need to test their assumptions about diagnoses, treatment and management, use the best research methods available and make their findings accessible.

Basic principles

Design

Every possible attempt should be made to reduce conscious and unconscious bias.

Sample size

Sample sizes should be calculated before research is initiated, as inappropriately small studies may lead to falsely negative findings.

Duration of study

The appropriate length of the study and time at which outcomes are measured, should be considered carefully as they can change over time. There may be a time-lag between treatment initiation and expected benefits (e.g. several weeks with antidepressants).

Timing of evaluations

Timing can cause methodological and ethical dilemmas. On the one hand it is desirable that all new treatments are initiated as soon as they are developed. On the other hand, some services do not work optimally at first and improve with practice (e.g. cardiac surgery). Early evaluation may give misleadingly negative results, preventing the use of beneficial treatments.

Outcome measures

These need to be valid, reliable and meaningful. Many evaluations can give falsely negative results because of insensitive outcome measures. A great deal of work remains to be done to improve outcome measures.

Types of study

Descriptive

Descriptive studies are undertaken to determine the frequency of a disease, the characteristics of people suffering from it, and where and when it occurs. Descriptive studies can either be cross-sectional (i.e. conducted at one point in time) or longitudinal (i. e. where observations are repeated at least once over a time period).

Analytic

Analytic studies investigate the determinants or factors associated with a disease. There are two types of analytic study: case-control studies and cohort studies; the former are retrospective and the latter prospective. A case-control study starts at the point of identifying a group of people with the disease and compares them with a control group. A cohort study compares a group of people exposed to the suspected determinant/factor with a group not exposed (Barker & Hall, 1991).

Experimental

Experimental studies are based on the classic scientific approach of formulating a hypothesis and conducting a controlled experiment to test it. This approach is considerably more difficult to adopt with humans than with animals or chemicals. Trials can be used to test hypotheses that have been generated from observational data, to quantify the effectiveness of certain treatments or to evaluate service provision. The randomised controlled trial, by using a study group and a control group which are identical in all respects apart from the factor or intervention in question, reduces the effect of confounding variables and clarifies whether or not associations are causal. Randomised controlled trials are often considered the gold standard of evaluative research.

Ethical principles

Truth-telling

It must be an overriding principle that patients are told the truth as often as possible. The use of placebos obviously pose many ethical questions. However, the importance of the placebo effect cannot be underestimated,

particularly when alternative treatments are unavailable. There is evidence that informing people that they are on a placebo changes the outcomes (Hawthorne effect).

Informed consent

The aims of informed consent are two-fold: to guard the individuality and autonomy of patients within the health care system and to protect their rights of privacy and the right to be left alone. Informed consent requires full description of the proposed research project, and its intentions. However, on some occasions detailed description of the hypothesis may influence the research findings. It is generally agreed that patients should be fully informed of possible risks (minimal and maximal) and benefits. This information is often not available.

Confidentiality and privacy

Risks should be reduced as far as possible. All attempts should be made to maximise the personal privacy of all data collection records; names and addresses should be used as little as possible and certainly should not be stored on computers, alternative identifiers should be used. Many of these ethical aspects are particularly difficult in old age psychiatry and need careful consideration.

Right to refuse

Patients have an unquestionable right to refuse to participate in research as well as treatment. No professional has the right to breach the autonomy of an individual. Participants also have the right to withdraw from studies at any time, not only at their commencement. This obviously conflicts with the interests of researchers, who for good quality research require high response rates and low drop-out rates. These can usually be achieved with good communication.

The individual versus society

It is the role of clinicians and health care professionals to respond to the needs of individual patients, and their best interests must be paramount. On the other hand, epidemiological research is focused on communities, or groups of people, in order to maximise the benefit to society at large. At times these interests conflict.

Health care policy

The trial of a new drug is more likely to be regarded as research than is the initiation of a change in care policy, for example, the closing of mental

hospitals. However, changes in health or social care delivery systems should warrant the same rigorous evaluation and monitoring as would a new drug. Scant attention has been paid to the ethics of experimentation in health and social care systems. It is still not required that new health care systems, changes to these systems or even reductions in services, be monitored or evaluated.

Stages in a research project

Definition of hypotheses and objectives

Before starting a research project it is crucial to develop a clear hypothesis and to formulate the research questions to be addressed. It is necessary to develop these before considering the design of a study, as they will dictate the aims and objectives of the project. Clear definitions are required for the disease and the interventions to be investigated. A thorough search of the literature will indicate the originality and value of the proposed project.

Seeking advice

Time invested in discussions with 'experts' from different professions (depending on the nature of the project) will pay handsome dividends. Seek advice at the outset. Poorly designed studies are no quicker to execute, analyse, interpret or write up, but are unlikely to find welcoming editors. Experts are often unwilling to assist in the analysis or interpretation of a poorly designed project.

Selection of a sample

Populations are usually large numbers of people in a defined context. These can be either unselected or groups selected because of: admission to hospital, attendance at out-patients or primary care, by socio-demographic or medical characteristics. A sample is a subset of a population in question, hence the use of a random sample. It is crucial that the sample is representative of the population, which is why random samples are often used. The findings of an appropriate sample should be generalisable to the population in question. The results of drug trials undertaken on young healthy medical students are unlikely to be applicable to an older population.

The size of the sample is also very important, particularly in experimental studies or if comparisons of subgroups are to be made. The appropriate sample size should be calculated early in the study design, with the advice of a statistician or epidemiologist. To maintain the representative nature of the initial sample, high response rates are essential at each stage. Losses through attrition (e.g. failure to trace, loss of notes, lack of contact, refusal

to participate and loss to follow-up) will jeopardise the representativeness and consequently generalisability of the findings as non-responders are likely to have different characteristics from responders. Ideally non-response and loss to follow-up should not exceed 10%.

When a control group is required careful thought is essential; if the controls are inappropriate the results of an investigation are of minimal value. In analytic studies, to avoid confounding bias, the control group must resemble the study group in certain specified characteristics. Observations or measurements made on the control group must be directly comparable to those made on the study group. In randomised controlled trials the control and study group should be identical in all respects apart from the intervention.

Choice of instruments

Before commencing any research project it is necessary to decide what observations are to be made and which instruments are to be used; above all, wherever possible, those that are standardised (valid and reliable). To be valid an instrument must measure what it is intended to measure with high sensitivity and specificity. Accurate measurements are repeatable (i.e. remain the same when elicited more than once). There are two forms of observer bias/error to avoid or minimise: between-observer variation and within-observer variation. These can arise in laboratory tests, mechanical measures or questionnaires.

It is unwise to design original questionnaires but preferable to benefit from the mistakes and expertise of others. Wherever possible, aspiring researchers should employ previously used and validated questionnaires; this will, as well as saving a great deal of time and possible error, enable the results to be compared with those of others. There is an increasing number of such questionnaires and interview schedules available; social scientists, clinicians and epidemiologists working in the area in question can provide useful advice and guidance on the selection from the available menu. If standard questionnaires are not available again advice should be sought from experienced researchers. There is no virtue, only frustration, in repeating the mistakes others have made. Advice and guidance on the design of data collection sheets (for recording clinical data from notes etc.) will pay dividends. Particular care is required when designing and selecting questionnaires or interview schedules for older people.

Ethical approval

In the past most research was undertaken without formal ethical approval. This is no longer the case. All research projects need to be submitted to an appropriate ethical committee, even before applying for funding. Studies involving hospital and community may need to receive ethical

approval from both committees. Generally, ethical approval is needed from each district in which a study is to be conducted. Hence a multi-centre study will require ethical approval from several districts.

Funding

The least complicated strategy is to conduct research that requires no extra funding but can be executed, with appropriate cooperation, within the available resources. The application for research funds will, even if successful, delay a project by at least six months. There are many different sources of funding: research councils, district health authorities, offices of research and development, research foundations, drug companies and charitable trusts and foundations. Information concerning each is usually available in medical libraries.

Execution

Collaborating colleagues, staff and study population need to be appropriately informed of the nature and purpose of the study. Colleagues and staff will need thorough initial and ongoing training to maintain standardisation. We all need to bear in mind that patients/members of the general population are under no obligation to participate in research activities; they do so only by grace and favour!

Analyses and interpretation

Advice on analyses at an early stage is essential, this can be gleaned from departments of (medical) statistics or epidemiology (public health). The presentation and discussion of findings with colleagues and other interested professionals is invaluable; they may be able to offer completely different perspectives on the findings and interpretations. A manuscript benefits enormously by being read and criticised by several people prior to submission to a journal.

Box 20.1 Stages of a research project

Definition of hypotheses and objectives
Seeking advice
Selecting of a sample
Choice of instruments
Ethical approval
Funding
Execution
Analyses and interpretation

Specific problems and challenges

Diagnostic criteria

Since Kay's seminal work (Kay *et al*, 1964) there have been at least 25 population surveys of depression in older people, most of which have been undertaken in the UK or USA. The results have differed enormously, reflecting the variation in criteria, instruments and populations selected. Standardised criteria in the form of ICD-10 (World Health Organization, 1992) and DSM-IV (American Psychiatric Association, 1994) are helpful, although neither has sections specifically for older people and problems have arisen with late-onset schizophrenia (see Chapter 10).

Diagnostic instruments

Many of the instruments which have been used are more suitable for hospitalised patients of younger age groups than community-based older populations. Many schedules were derived from the symptomatology of younger adults and hence many of the questions involve possible physical symptoms. Schedules such as the Geriatric Depression Scale have been developed to avoid these items where possible (Yesavage *et al*, 1983) (see Chapter 1).

Populations

Ideally, study populations should include people who are in residential care, as they tend to have a higher prevalence of mental illness. Inclusion or otherwise of residential or hospital patients can have a large effect on epidemiological studies. Similarly treatment outcomes may vary between these populations.

Association

People who are in residential care tend to have a higher prevalence of mental illness. The nature and direction of this association requires further investigation: are people selected for residential care because they are depressed or have dementia, or because they become so after admission? In the community, older people do not have an excess of depressive disorder (see Chapter 7).

Identifying patients

Many depressed older people are not identified in the community and very often no action is taken when it is identified to investigate or treat their mental illness (Gruer, 1975; Macdonald, 1986; Vetter *et al*, 1986). One way of improving the detection and treatment may be through using

screening instruments and protocols. There is room for further work to develop the use of assessment instruments which can be used easily and reliably in the community by health visitors, practice nurses and other professionals, particularly in the light of the requirement upon general practitioners to assess those aged 75 years and over. Strategies for the multi-phasic assessment of older people in the community could enable earlier diagnosis and facilitate optimal management.

Physical illness

Many studies have shown associations between depression and physical illness (Vetter *et al*, 1986). For example, a high proportion of stroke sufferers develop depression (Robinson *et al*, 1984; Ebrahim *et al*, 1987). Depression is also more common among people with Parkinson's disease and Huntington's disease. Associations with many types of malignancies have been suggested and need further exploration. Raised rates of depression among patients after myocardial infarction have been well-documented, but reliable predictors have yet to be identified. Increased physical disability, dependency on others and reduction in active social life may also be important. Medications can also be responsible for the onset of depression (Ouslander, 1982).

Opinion varies as to whether depression can produce physical illness. Some research gives weight to the view that there is a raised mortality from cardiovascular disease in men within the first six months of their being widowed (Parkes *et al*, 1969). The lay view would certainly support this hypothesis. Anxiety, depression and insomnia have all been implicated in subsequent myocardial infarction in small studies (Kuller, 1978). Prospective studies with larger study populations may illuminate the relationship between physical and mental health.

Box 20.2 Possible reasons for the association between depression and physical illness (adapted from Murphy, 1992)

Depression may be a direct consequence of the cerebral organic effects of certain specified physical disorders.

Depression could be a consequence of treatments for physical illness.

Depression may result from a psychological reaction to physical illness and process of adaptation to future disability.

Depression may predispose to the onset of physical disease. The behavioural consequences of depression may cause physical illness (e.g. self-neglect).

Social factors

The exploration of the involvement of social factors resulting in mental disorder in old age is of great importance because of the implications for prevention. Again, the lay public do not doubt these associations but more empirical evidence is needed concerning: poverty, social class, education, loneliness, social isolation, support networks, retirement, sensory impairment and life events. Significant associations have been demonstrated with some of these factors but a longitudinal approach is required to investigate causality.

Brown & Harris (1978) and Murphy (1982) identified the role in depression of life events such as bereavement, serious physical illness, financial loss and enforced relocation. However, not everyone experiencing these life events develops depression. Research is needed into the factors that protect some people from depression after life events. Murphy (1982) and others have indicated the ameliorating effects of social networks and close confidants.

Environmental interventions are important in dementia (see Chapter 6). The benefits of these types of strategies need to be carefully evaluated, particularly in residential settings where little work has been undertaken. New institutions provide opportunities for the evaluation of different types of architecture and design.

Drug studies

Medications have developed enormously in the past 10 years, with new antidepressants being introduced virtually every year. Reviews do not consistently favour one drug more than another (Veitch, 1982; Busse & Simpson, 1983). Selection is largely based upon cost, side-effects, compliance, toxicity in overdose and the individual experience of clinicians. Most drug trials in the past have been undertaken with younger adults; the results of which cannot be assumed to be valid for older populations. Optimum therapeutic levels are likely to be different in older people; some studies have indicated the benefits of lower doses in the elderly, while others argue that low doses may be less efficacious. General practitioners are increasingly prescribing the standard, once a day, doses of selective serotonin reuptake inhibitors. Antidepressants may cause dizziness and falls (Campbell *et al*, 1989); these and other adverse effects need to be investigated.

Studies to evaluate drug treatments are fraught with difficulties; patients need to be followed-up for a reasonable time, high compliance rates are difficult to achieve and many patients, because of a poor response or side-effects, require a change in medication. These factors necessitate large sample sizes. Most studies are too short in duration to investigate remission rates. Studies become even more complicated if combined treatments are evaluated (as they should be). To date, most evaluations

of treatment have been undertaken in hospitals. More work is necessary in primary care where most older people with depression are seen.

Currently, the most hopeful drug therapies for mild to moderate Alzheimer's disease are the acetylcholinesterase inhibitors. Donepezil is the first one to gain a licence in the UK (Kelly *et al*, 1997), although tacrine was launched in the United States in 1993. These medications appear to delay deterioration in cognitive function and may delay nursing home admission (Knopman *et al*, 1996). Tacrine offers some potential benefit to about a third to a half of patients but a significant minority (a third) suffer side-effects and half of these cease the therapy (Knapp *et al*, 1994). Donepezil appears to have fewer side-effects. It is possible that the introduction of these medications, or newer ones to follow, may alter the management of Alzheimer's disease, with a new emphasis on early diagnosis.

Many drugs, including neuroleptics, have been used for the treatment of symptoms in dementia and there is a wealth of research potential in this area. Tricyclic antidepressants have been used with benefit in some patients with dementia and depression, but there is the possibility of increased cognitive impairment; other antidepressants need to be evaluated. Similarly, the anticholinergic component of many neuroleptics, prescribed for behavioural problems, may exacerbate Alzheimer's disease. Further work is needed to identify those patients who will benefit from which symptom-reducing medications.

Psychotherapy

Psychotherapy in conjunction with other treatments may benefit people living in the community or residential homes, or as hospital in-patients. However, there is a paucity of work evaluating such interventions. Clinical psychologists are increasingly working in the primary care sector; their effectiveness with patients who have mild or fluctuating depression, or who have been recently bereaved has yet to be established. Similarly, the role of cognitive therapy and self-help approaches needs evaluating in residential and primary care settings. These therapies are unlikely to gain wide use until they have been evaluated rigorously and shown to be effective.

Long-term outcome

Appropriate measures of long-term outcome for depressed older people and their carers need to be developed. Chronic disability and relapse are common (Post, 1972; Murphy, 1982); the identification of predictors for these conditions may allow the development of prevention packages, such as prophylactic management strategies for patients and their carers. Since social factors together with the severity and nature of the illness influence long-term outcome (Post, 1972), social interventions may be beneficial.

Measurement of outcome in dementia should be broad in nature, including not only memory, thinking and behaviour but also disability and quality of life, as assessed by patients and their carers. Effectiveness should be assessed long-term as well as in the short term.

Services

There has been little evaluation of after-care and service provision for people recovering from a depressive episode, or those with chronic depression. Some people only need support in the immediate post-discharge period, while others may require long-term help. Services are, to an extent, available for carers; this may be in the form of advice, day care or respite care. There is evidence that carers of depressed elderly people are often suffering from depression themselves (Jones & Peters, 1992) (see Chapter 18). The causality and direction of this association needs further investigation and preventive strategies need to be developed and evaluated.

A large proportion of people with Alzheimer's disease live in residential care, nursing homes or long-stay hospitals. Inadequate work has been undertaken to assess the quality of care in these institutions, and baseline standards have yet to be established. The design, organisation and running of homes have tangible consequences for the quality of life of people with dementia. Many residents, for example, are taking inappropriate medication or too many medications (Gosney *et al*, 1989). Institutions are ideal locations for introducing and evaluating new strategies for the management of people with dementia.

Services try to enable people to live in the community as long as possible and reduce the burden of care on carers (Department of Health, 1989). Studies have examined the effects of this policy upon carers and their quality of life (Levin, 1983; Gilhooly, 1984; Jones & Peters, 1992) (see Chapter 18). Any evaluation of management should include assessment of both patient's and carer's own quality of life (Howard & Rockwood, 1995) and use of community and institutional services. There is a lack of flexible, planned respite care. It is important to develop innovative forms of respite which are consumer-needs led; voluntary organisations have begun to address these needs. While there has been some evaluation of respite care there is more to do, on larger samples with controlled populations. Different models of supporting carers – as individuals, or in groups – need to be developed and evaluated. Such evaluations are best undertaken by multi-disciplinary groups, where the clinical perspective is crucial.

Memory clinics

In recent years, memory clinics have been developed in the USA and UK to assess and manage people with memory disorders. Since memory clinics

Box 20.3 Specific problems and challenges in old age psychiatry research

Treatment involves several types of intervention, often in combination
 Treatment is commonly long-term and relapses occur
 There are many interacting variables to take into account
 Treatment involves all aspects of life including social, spiritual, functional and quality of life
 Management and care involves other agencies and informal carers
 Cultural contexts need to be taken into account
 Treatments are often in combinations and therefore need to be evaluated in combinations as well as independently

involve several different disciplines, they provide particularly valuable environments to undertake research into diagnosis, treatment and management (Bayer *et al*, 1990). Some areas of the UK have invested in community memory teams to counter the perceived neglect of health and social services in this area. Rigorous evaluations will be required to compare the effectiveness of a specialised team with standard health and social services provision.

Future areas for research

There are many areas which offer the potential for new research, some of which are listed in Box 20.4. As society changes and new diagnoses and managements arise, so new areas of research will emerge. Competition for research grants is often intense but many organisations are realising that older people and their mental health have been relatively neglected.

Box 20.4 Future areas for research (SUCCESS)

Suicide: more common in older people but under researched
 Users' opinions: encouraged by NHS reforms
 Carers: belatedly recognised to be important
 Crime abuse: the effects of abuse and the fear of crime on older people
 Ethnicity: as ethnic minority groups in the UK age
 Strategies: to prevent violence against or abuse of older people
 Stabilising: Alzheimer's disease with medications

Conclusion

The multi-dimensional nature of old age psychiatry research requires collaboration with primary health care services, social service departments, community health and other hospital specialities (Jolley & Arie, 1978; Jolley & Jolley, 1991). Research expertise will increasingly need to be multi-disciplinary and include biological, epidemiological and social perspectives.

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