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Intervention Studies among Elderly People

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In spite of a large number of descriptive studies on the care of the elderly, there are few examples of intervention studies in the Nordic countries (1). The aim of an intervention study is to alter any specified condition in the society, and at the same time to study the course and the result of the intervention by scientific methods (2).

Care of the elderly is undergoing rapid change in the Nordic countries as well as in most Western countries. There is a trend to replace institutional care by domiciliary care, although the development is not the same all over. Geographic variations contribute to the difficulties in elaborating standard methods for evaluation of the care of the elderly (3). As health budgets decrease and the demands on the elderly and their families increase, there is a stronger need to replace *beliefs* with *facts* about the health care of the elderly. The empirical evidence from controlled intervention studies can provide these needed facts.

Some intervention studies have been completed in the Nordic countries. Some of the methodological and practical experiences from these studies are presented elsewhere in this journal (1, 2, 3, 4, 5). This article will summarize some of the Nordic experiences in this field.

GENERAL PROBLEMS

Methodological problems include the lack of standard instruments in data collection and analysis. The difficulties in discriminating between normal and pathologic aging creates problems in case finding and in the epidemiological aspects of such studies. Non-definable disease could be an operational definition of normal aging (6). The interview part of studies among elderly people includes problems such as impaired memory, dementia, hearing loss,

speech difficulties, suspicious, and general physical incapacity.

Timing includes the problem of a short remaining lifespan which restricts the observation period. On the other hand many years of observation may not be necessary because of the high prevalence and incidence of morbidity in old age.

Uncontrolled conditions are a problem in any intervention study. Most intervention studies are multifactorial in their approach. Thus it is important to be aware of, and record, all alterations during the study which are outside the influence of the study. This helps to improve the validity of the interpretation of the results.

Cure or care raises the question of the possibility of evaluating health care: The aging process leads to deterioration while the aim of medical treatment is improvement. Medical treatment and proper care may delay age-related incapability, and a slower decline in functions may well be a positive outcome in old age.

SETTING THE AIMS OF THE INTERVENTION STUDIES

In the literature on evaluation research the importance of defining the aims of the study is underlined (7). The aims must be specified from the material at hand, the relevant data and the evaluation instrument. From the beginning the data collection should be planned in order to answer the questions set up in the aims of the study. A common mistake is to include far too many items in the data collecting instrument, which later show up as irrelevant to the study.

The work up period must be designed for a realistic intervention for the target population. There are a number of obstacles in the real world, such as

shortage of home helpers, inadequate reporting systems, waiting lists for various services for the frail old person, and non-responders among those persons who could contribute the most interesting material to your study. Consequently the enthusiastic study design may be distorted by circumstances beyond the control of the researchers. Any observed positive result may arise from other factors not taken into consideration during the planning period.

Some studies have proven that the positive effects may not show up until late in the observation period (5). There are studies where the positive effect comes after a short observation time, and long-time follow-up is needed to prove any long-lasting effect (8). In early evaluation there may be a danger of a "Hawthorne-effect", where the evaluation itself creates some of the observed changes. In late evaluation the difficulty is to control for a variety of factors influencing your results in an unpredictable way.

PLANNING THE INTERVENTION STUDIES

The planning must be adapted to the type of study. Therefore one standard procedure cannot be described, but some common factors can be considered in the planning period in most projects.

Formal and practical planning

Political support is absolutely vital. This means that in most cases you must apply for political acceptance to start your projects. You must apply for permission to use the census, building up a nominative data register, and collecting sensitive data such as information about health, social services and economics. If you plan for an interview study, you have to inform your target population in advance. Normally you post an introductory letter, and this must be officially certified, in Norway by The National Bureau of Statistics. In the letter you must make clear that participation in the study is voluntary.

The politicians often consider intervention, which supplies part of the population with improved medical service, as a political and ethical problem. In such cases you probably should not declare your experimental design publically while doing the field work. In addition you must secure a

sufficient post-project service for your target population.

Finances often come from multiple sources and not only from research funds. The different sources often have different application and decision procedures, and you may have an acceptance from one source on the condition that the others provide their parts. Often you receive less than you applied for, and this may alter the stand of the other sources which do not compensate for the loss. The result may be a time consuming alteration of the study design and perhaps a delay of a year. In addition all external financial sources should receive an annual revenue.

If members of the study population will accrue expenses, transportation costs, for example, these should be covered by the project fund or in accordance with ordinary regulations when legitimated in advance.

Personnel must sometimes be recruited specifically for the study. This normally includes at least one researcher in charge of the study. If you include more professionals, the research approach may be more sophisticated. Ordinary staff-members and students are useful, for example in data registration, interviews and practical intervention, and this strategy makes your study more easily accepted and more readily adaptable in the field. The more unskilled personnel you depend on, the more effort it requires to make your data reliable. In most projects you need access to a trained, often full time clerk.

Professional support includes affiliation to a research institution, most often a university institute. Preferably the institute should be the formal organisation to employ the external research personnel. You strongly need such a scientific input while doing the field work. The institute may have, or may assist in supplying, a research supervisor, a panel of referees, and the necessary statistical competence.

It is preferable to ask for advice from those professionals who are most competent in your particular field. Some very competent scientists have a profound skepticism to intervention studies which they view as "pseudo-science". It is wise to listen to their arguments, because it is better to deal with your despair before beginning your work than to argue for a result based on incorrect conditions afterwards.

If, like Williamson in the UK (9), you wish to

look into undiagnosed medical conditions among elderly people, you may find that your GP colleagues dislike your intention. They do not want anybody to "look into their cards". You should therefore ask them for advice at an early time, inform them carefully about your plans, and offer them something in return which may be of value for all parties involved. This may be a patient report after a medical examination or preliminary statistics related to their own practice.

A *steering committee* may be useful and should be appointed in the very beginning. All parties involved in financing or leading the project could participate as members. There are few reports of an elderly person being a member of the committee even though the elderly are the target population. There may be better ways of obtaining input from the elderly, for example by regular informal discussions with outspoken members of the elderly and their caretakers. Any steering committee should meet regularly, with a secretary responsible for the agenda and a written report.

Timing. Most often you underestimate the need for a long planning period, often a third of the total time available. At the other end you often set aside too little time for data processing and writing. Before publication you normally should consult your steering committee and your board of referees. Thus, an efficient division of time involves one third for planning, one third for data collection, intervention and evaluation and the last third for data processing, statistical analyses, writing and publication.

Methodological preparations

The material. How to set age limits depends on the type of study. Where prevention is an important aspect, a population of 70 years and over is useful, whereas a minimum age limit of 80 years is more convenient when studying multiorgan failure and functional dependency.

There are available statistical methods for determining an appropriate sample size. Nevertheless calculation of power are rarely used in the planning of studies, and the size is more often a result of the length of the study or amount of money available. The size is closely related to significance testing which has as its objective to reduce to an acceptable level the risk of a misleading result.

The sample size depends among other factors, on the power you wish, and a minimum of 90% is

preferable. You also must specify your significance level. The type and number of variables and the number of subsamples you use in your analyses, influence the sample size. It is wise to consult a statistician to specify your sample size, and to look up some of the literature (10, 11) and statistical textbooks (12, 13) in the field.

In some intervention studies you need a control group. If the controls are located in the same geographical area as the study group, you may have a problem of restricting your intervention to merely your study group. If your control group is in a different area, you have to consider the effect of different environments.

In intervention studies non-responders often are either very fit or very frail old persons (8). You need a strategy to minimize the number of non-responders. If your method is home visits you should probably try some sort of effort three times before dropping the case.

Methods. If possible one should stick to internationally accepted research methods for data collection, measurements and evaluation. If you need your own design, the instrument should be tested in a pilot. Is the method readily accepted by the examiner and the old person? Does the method measure what is intended? Is a written text easily understood? Does the instrument include all possible alternatives, for example in a questionnaire?

If you have a number of untrained observers or data collectors, you need a training period in handling the method, and to test the variability over time and between different observers. A protocol with operational definitions for the data collection should be available, and typical examples are often very helpful. Interpretation or classification problems should be dealt with by one of the responsible professionals.

Qualitative methods include careful descriptions of processes, attitudes, case reports and historical research methods. Audio- and/or videotape recordings may be very useful in such studies.

Statistical methods should be planned at the same time as the data collection instruments, including preparation for the differences between nominal, ordinal and continuous data, as well as parametric and nonparametric data. In most intervention studies it is wise to plan for multifactorial statistical analyses. Statistically significant differences, without any preceeding theory, often lead to wrong conclusions. You may have found a spurious

condition, or a result generating new hypotheses, and not an answer to questions you had asked in the beginning. This is perhaps the main reason for carefully defining your hypotheses and the evaluation methods when planning an intervention study.

Evaluation methods must be developed in the planning period and not when most of the study is already done. In a result-oriented study you may compare the outcome in your intervention group with the control group. If you have no control group, you have to look into your group before and after intervention with the same methods. The evaluation may be an assessment of the extent to which there is a change in a certain intended direction.

In a process-oriented study you need a qualitative description of your observations. One example is different attitudes among politicians when discussing the need for an increased number of homehelpers in the coming year.

THE PRACTICAL IMPLEMENTATION OF INTERVENTION STUDIES

Original plans are very often upset by unexpected events. In order to make revised plans and cope with a new situation, it is important for the project manager to meet regularly with the staff involved and to keep in touch with a supervisor or a steering committee. If the researcher is an outside observer with no active participation in the intervention program, someone should be appointed as an executive responsible for the day-to-day work and to solve minor problems. If a study is led in different areas, there should be an area supervisor assigned to each group.

During the intervention it is important to keep a written record of the day-to-day experience. This may include the time for the different steps, observations which are not integrated in the standard data collection and altered conditions in the society at large with potential influence on the result of the study. In such a diary valuable qualitative data can be recorded.

Fieldworkers do not always appreciate the need for objectivity and accuracy, and this may lead to strained relations between the researcher in charge and the rest of the staff. In striving for a common standard the research manager, together with any area supervisor, should meet regularly to discuss any problems related to the methods in use. If your population samples come from different areas, such

meetings are vitally important to ensure against unacceptable variations in methods. If the study takes place at a number of different locations, the research manager should keep in regular contact with all the groups by telephone and by frequent personal visits.

There may be much anxiety from old persons when selected for an intervention study. Many tend to reject participation with some saying they feel too weak, and others claiming a fear of not answering the questions correctly. Some are unable to read your introductory message, some are too confused or demented to understand what it is all about, and some have a deficient memory with resulting incapacities. Others, through fears brought on by the well-published criminality against the elderly, refuse to open the door to unknown persons. For example, one demented, frail woman heard the bell ring, opened the door just a little, kept the safety chain on, and asked who was there. The male student was equipped with an identity card as an interviewer, which he showed immediately. "Thank you", was the response of the scared old woman, as she quickly grasped the card and shut the door. Experiences like this underline the importance of preparing your target population for what is coming, and if possible you should ally with some relatives, a home helper or anyone in whom the old person has confidence.

Intervention studies include both scientific and practical work at the same time. This may be a problem, because you wish to collect your baseline data as fast as possible. At the same time you must act on some of your observations, and the intervention requires more and more of your time. Thus you may end up with a constant conflict between theory and practice, data collection and intervention, reading and writing. The only way out of this is to organize your time in recognition of this dilemma. You can, for example, divide the day or the week into two parts, one for each side of your study.

THE EVALUATION PERIOD

All your data should be entered and processed as quickly as possible. Preliminary results should be available for the staff members, other participants, the supervisor and any steering committee as soon as possible, always keeping in mind the danger of influence of such knowledge in the data collection ahead.

The evaluation of intervention studies include "hard end points" such as mortality, numbers of days in institutions, all quantitative data which is available from your data files. Qualitative data such as case reports or observations in close contact with exhausted relatives are quite as important to include in a written report.

Politicians and administrators are trained to interpret costs and benefits. In order to implement your ideas from your intervention study into common practice, the politicians depend on your estimates on alternative costs. Therefore any intervention study should deal with the financial consequences of the proposals emerging from the study. This does not mean that every intervention study must include a cost-benefit or cost-effectiveness analysis. But some gross estimates on economic aspects should be reported.

THE PUBLICATION STRATEGY

The type of publication depends on the scientific ambition of the research project and who you regard as the target population for your report. In some studies you aim to deal with a local situation which does not have any general interest. Such studies could be published in some sort of internal report without further distribution. More often your intervention is of special interest, not only for your local institution, but for your local community. In such cases you should at least publish a report for distribution in your community among professionals, administrators and politicians. In these situations parts of the study are of more general interest, and the results should be available for a wider distribution, for example to all municipalities or counties.

When intervention studies are well planned and the methods are worked out according to scientific standards, the results should be published in professional journals. Some parts of the study may be of special national interest and are convenient for publication in national journals. Other parts of the study may be of more general interest and should be internationally published.

In those cases where your target for the publication is local decision-makers as well as international scientists, you have the problem of double publication. This may include articles in professional journals as well as a short, popular version for non-professional decision-makers and those with a spe-

cial interest in the field. From experience, this double set of publications may be a heavy burden, because you have to adapt to different expectations, using simple words and explanations in the popular report and recognized scientific standards in your articles. In addition there is the problem of publishing studies in journals when the results already are published elsewhere.

The research manager should have the main responsibility for the publication and should be the first author. The problem of co-authors should be clarified as early as possible in the project period. If possible, staff members with different professions could publish the relevant parts of the report or special articles in their professional journals.

Many reports from intervention studies include a lot of tables. Figures are important, but in the written report some of the tables should preferably be printed as appendices for those with a special interest.

Some sort of feedback should be available for the target population. For example, articles in newspapers and magazines or interviews in other mass media could provide needed feedback. The written publication should be followed up with lectures and seminars in order to spread the messages from the study.

SUMMARY

There are not many reports of Nordic intervention studies on the health and medical care of the elderly. Nevertheless much knowledge about old age is available and should be applied in practice under controlled conditions. In this overview article the authors present some experience from four of the Nordic countries to encourage further intervention studies, and focus some important aspects to be taken into consideration.

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