

DOING A PILOT STUDY: WHY IS IT ESSENTIAL?

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ABSTRACT

A pilot study is one of the essential stages in a research project. This paper aims to describe the importance of and steps involved in executing a pilot study by using an example of a descriptive study in primary care. The process of testing the feasibility of the project proposal, recruitment of subjects, research tool and data analysis was reported. We conclude that a pilot study is necessary and useful in providing the groundwork in a research project.

Key words: pilot study, primary care

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INTRODUCTION

A pilot study can be defined as a 'small study to test research protocols, data collection instruments, sample recruitment strategies, and other research techniques in preparation for a larger study.¹ A pilot study is one of the important stages in a research project and is conducted to identify potential problem areas and deficiencies in the research instruments and protocol prior to implementation during the full study.^{2,3} It can also help members of the research team become familiar with the procedures in the protocol, and can help them decide between two competing study methods, such as using interviews rather than a self-administered questionnaire.⁴

This article aims to describe the steps involved in undertaking a pilot study by using as an example a proposed survey of the prevalence of insomnia and its impact on daily function amongst Malaysian primary care patients. A few studies conducted in primary care settings have reported that the primary care population has a higher prevalence of insomnia (64-69%) than the general population and those with chronic insomnia had significant impact on daytime functioning and psychological health.^{5,6} The pilot study was conducted on patients, aged 18 and above, attending two government health centres and six general practice clinics in Peninsular Malaysia.

METHODS

The pilot study comprised several components which are summarised in Figure 1.

1. To determine the feasibility of the study protocol

A pilot study was conducted in a general practitioner clinic in Kuala Lumpur from July to September 2005. Pilot studies for all other centres were done in early November 2005. In the first pilot, the provisional study protocol was strictly adhered to, that is, a small-scale version of the complete survey was tested, from patient recruitment to data analysis. The researchers agreed to enrol 20 adult patients aged 18 years and over. Training of the doctors in charge and research assistants in other centres were simultaneously conducted to establish their understanding of the project aims and protocol and to determine the number of research assistants needed for the study.

2. Recruitment of subjects

The doctors invited subjects to participate in the study, with adequate time given for the patients to consider whether they wished to participate. Patients demonstrated their consent by signing the consent form. Then they were handed the first questionnaire that sought information on the presence of insomnia symptoms. If insomnia was present, they were given a second questionnaire by the research assistant that sought information on the impact of insomnia on daytime function and psychological health. The response rate was recorded and the research assistant observed that data collection progressed smoothly.

3. Testing the measurement instrument

The measurement instrument (a questionnaire) required self-completion by patients with the assistance of several research assistants. An important factor was to ensure that the questionnaire items accurately addressed the research questions. The pilot also tested whether the questionnaire was comprehensible and appropriate, and that the

questions were well defined, clearly understood and presented in a consistent manner. Patient information statements and consent forms were also tested for comprehension.

The questionnaire was divided into 3 sections that related to a) socio-demographic characteristics of respondents; b) sleep, with items seeking information on the sleep pattern, impact of inadequate sleep on daytime function and psychological health; and c) the Hospital Anxiety and Depression scale (HADS)⁷ to screen for symptoms of anxiety and depression. The HADS has been translated and validated in Malaysia⁸. The questionnaire was produced in English and Bahasa Malaysia versions and was piloted 4 times, using 10-12 subjects each time.

Issues that were observed among patients in the pilot of the questionnaire included:

- Ability to comprehend the instructions in the covering letter
- Understanding of questionnaire items, the terms used, the sequence of questions and the flow of statements
- The format, including the font and lay out
- Length of the questionnaire (i.e. the time taken to complete the questionnaire)
- Other comments by patients.

All comments were taken into consideration and errors amended and re-piloted until no further changes were considered necessary.

4. Data entry and analysis

Data from the 20 subjects were entered into a computer by a research assistant who was not involved in data collection. Entry was directly into the Statistical Package for Social Sciences (SPSS) program, with specific codes used for each questionnaire item. Data were then analysed using SPSS version 11.5.

The analysis was mainly descriptive, with data about age, total hours of sleep and total hours of time spent in bed, plus other items, being analysed for their mean, median, modal, minimum and maximum values.

To compare the categorical variables such as gender, ethnic group and employment status with insomnia symptoms, a χ^2 test of association or a Fisher exact test were used. To compare ordinal data such as age group, marital status and educational level with insomnia symptoms, a χ^2 test for trend was used. To compare the difference in means between the insomnia and non-insomnia groups, independent t tests were used. Statistical significance was set at $p < 0.05$.

RESULTS

1. The feasibility of the study protocol

The time taken by the doctor to explain the research project and obtain consent from the participants was about 3-5 minutes. The study procedures for data collection encountered some initial problems, with the research assistants unsure how to guide and assist the subjects due to a lack of familiarity with the questions. This difficulty was overcome after 3 or 4 subjects.

In view of the number of subjects to be recruited for the full study, it appeared that each centre required two research assistants, with each spending an average of 15 minutes to guide a respondent. Two research assistants were deemed necessary because, they were the nurses working in the respective clinics, which have 2 working shifts (9am till 3pm and 3pm till 9pm).

Note that a pilot study should preferably be done using subjects from a population that is different from those recruited for the main study. Experience gained by subjects in the pilot study may bias the results of the main study if the same subjects are included.

2. Recruitment of subjects

All patients invited agreed to participate in the study. They filled in the questionnaires in the waiting room while waiting for their medications.

3. Testing the measurement instrument

On average, the respondents took about 10-15 minutes to complete the questionnaires. While they all attempted to respond to all questions, there were some items that they missed. This appeared to be because the questions were spaced too close to each other, causing some of the participants to miss a line.

There was considerable discrepancy in the answers to some of the items, either because they were too vague or due to a language barrier, resulting in participants not understanding the questions properly. This was observed with the items asking about sleep pattern and sleep efficiency.

For some of the items, the boxes were placed too close together which made it difficult for the research assist to identify which one the respondent had ticked. Reformatting was done to overcome this problem. There were also a few typographical errors noted and some of the coding for the HADS items was wrong. HADS has been widely used and validated in primary care and from this pilot study respondents encountered no difficulty understanding the items (in both languages).

4. Data entry and analysis

A basic descriptive statistical analysis was done. Out of the 20 subjects, 12 were females and all were from the Malay ethnic group. Six subjects had insomnia. Two of them experienced sleepiness during the daytime but did not meet the criteria for 'excessive daytime sleepiness' based on the Epworth Sleepiness Scale.⁹ None of them had anxiety or depression. No difficulties were encountered in conducting the analysis.

DISCUSSION

This pilot study has demonstrated that the study protocol is feasible. The project did not appear to be too disruptive to the clinic or have a significant impact on staff time. It also seemed to be acceptable to patients in the waiting room.

It was possible to recruit patients based on the inclusion criteria of the study, although by chance only Malay patients were included. In order for the sample to be more representative of primary care attendees and other ethnic groups, both government and private GP clinics of different geographical locations (north, central, south) as well as doctors from different ethnic groups will be invited to participate in the full study.

This study has demonstrated the effectiveness of a pilot study in identifying flaws in a questionnaire that after appropriate amendments can then be utilised in a full study. It has also provided a better understanding of how to implement the survey; in this case, the research assistants were required to provide patients with occasional help with the questionnaire and to check item completion. The use of more than one method of data collection, i.e. interviews and self-administered questionnaires is called "triangulation".

Data entry was not problematic, although in the final study a statistician will be involved with data analysis. Pilot studies can also be used to help calculate sample size by providing data about the likely responses to questionnaire items.

The steps in this pilot study demonstrate the benefits and the methods of this important phase of a research project. While studies using different designs, such as experimental

ones, will involve pilot testing of other instruments and protocols, the general principles apply. The lessons learned in this particular study can be applied elsewhere (see Box 1).

CONCLUSION

The decision to conduct a pilot study prior to embarking on the main research project can be a difficult one for researchers. Sometimes it is tempting to omit this step, especially if the main study has been reasonably well planned. Constraints of time and a rush to get on with the main study are common reasons for passing over pilot work. However, this approach is risky, as no matter how thoughtfully a study has been planned, there are likely to be unforeseen difficulties, as this paper has shown. The investment in time and resources is generally worthwhile.

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Box 1: The importance of a pilot study

- To determine the feasibility of the study protocol and identify weaknesses in a study.
- To test whether the study instrument(s), is asking the intended questions, whether the format is comprehensible and whether the selected validated tool is appropriate for the target population.
- To test the appropriateness of data collection using the selected interview technique (face-to-face or telephone) or self-completed questionnaire (postal or administered at the centre).
- To test the data collection process – the time taken to complete questionnaire, and the subjects' willingness to participate in the study.
- To test data entry, coding of the items, and appropriateness of statistical tests
- To obtain preliminary data for the primary outcome measure, in order to calculate a required sample size (especially in randomized control trials).

