The challenge of recruiting people with schizophrenia to a health promotion trial

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ABSTRACT

People with schizophrenia have an increased risk of coronary heart disease. This pilot study tested the feasibility of carrying out a randomised controlled trial to compare coronary heart disease prevention for this population through an enhanced occupational therapy support intervention versus a practice-based intervention. Difficulty in deciding whether to take part meant that 123 visits were made to 25 people with 12 ultimately providing informed consent. Participants' discussion at a subsequent focus group (n = 3) suggested a poor understanding of the study process. Distrust of randomisation suggests that randomised controlled trials may not be the best way to evaluate community-based interventions for people with schizophrenia.

Keywords

coronary disease; feasibility studies; mental health; pilot projects; schizophrenia.

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INTRODUCTION

Mortality from circulatory disease is 2.5 times higher among people with severe and enduring mental illnesses than the general population.[1] This may be related to the greater likelihood of smoking, lack of exercise, poor diet, obesity,[2] and the adverse effects of antipsychotic medication.[3]

A previous study did not find psychosis to be associated with lower uptake of cardiovascular screening in general practice,[4] however, screening is not synonymous with engaging people in lifestyle change. The aim of this pilot study was to examine the feasibility of a tailored intervention designed to lower the risk of coronary heart disease in people with schizophrenia and how this might be evaluated as part of a randomised controlled trial.

METHOD

Participants were registered with one inner city practice and had a diagnosis of schizophrenia. Local community mental health care coordinators made the initial approach and excluded people unable to provide informed consent. Contact was then made between a research occupational therapist and the potential participant and further meetings arranged to provide study information, and, where agreed, written informed consent was obtained.

Baseline measures were recorded in the participant's home and included questions about coronary heart disease history, lifestyle, medication use and current mental health. Weight, height and blood pressure were measured and finger prick tests used for random blood glucose, total cholesterol and high-density lipoprotein cholesterol. Participants were randomly allocated to either enhanced occupational therapist support or practice-based care.

Participants randomised to the enhanced occupational therapist support group were supported over the study period by the research occupational therapist to facilitate engagement in health promoting activities. For participants allocated to the practice-based care group, a letter

was sent from a practice nurse inviting the participant to attend the GP practice to discuss their lifestyle and provide health promotion. The primary outcome measure was change in coronary heart disease risk after 9 months.[5] On conclusion of the study, participants were invited to attend a focus group to explore in greater detail their experiences of study participation and to investigate participants' health beliefs.

RESULTS

A total of 36 eligible people were identified from the practice list (Figure 1). Of these, two individuals were identified as being unsuitable for the study and nine refused any contact with the research occupational therapist; the research occupational therapist contacted 25 people to explain the study. The total number of visits made to eligible candidates (*n* = 25) to secure the 12 study participants was 123 (a mean of 10.3 visits per recruit). Of the 12 who eventually consented, agreement to take part took up to nine research occupational therapist visits. The number of visits required to recruit each participant was due to a number of factors, including forgotten appointments by the potential participant, the individual's ability to assimilate the study information, and the perception that increased social contact with the research occupational therapist might terminate once consent was provided.

Baseline measures were recorded over two visits due to the perceived burden of the baseline interview. Eleven participants completed these indices at baseline without difficulty. At follow-up, four participants were reluctant to be weighed and six participants were unwilling to complete measures of mental health.

Of the 12 participants, six were randomised to each group. The nature of the enhanced support intervention varied but included advice regarding healthy eating and exercise. Although all participants smoked, none chose to address this. Frequency of contact with enhanced support participants varied and was flexible to accommodate fluctuating levels of mental ill health. For the six participants randomised to the practice-based care group, one responded to an invitation from the practice nurse and one attended the nurse before the letter was sent.

Of the 12 participants invited to the focus group, five agreed to attend although only three (two in the practice-based care group and one in the enhanced support group) actually attended. The process of study participation was discussed extensively. All three focus group participants were aware that the study was concerned with the relationship between mental and physical health and saw potential advantages of taking part. There was not a clear understanding of the process of randomisation with

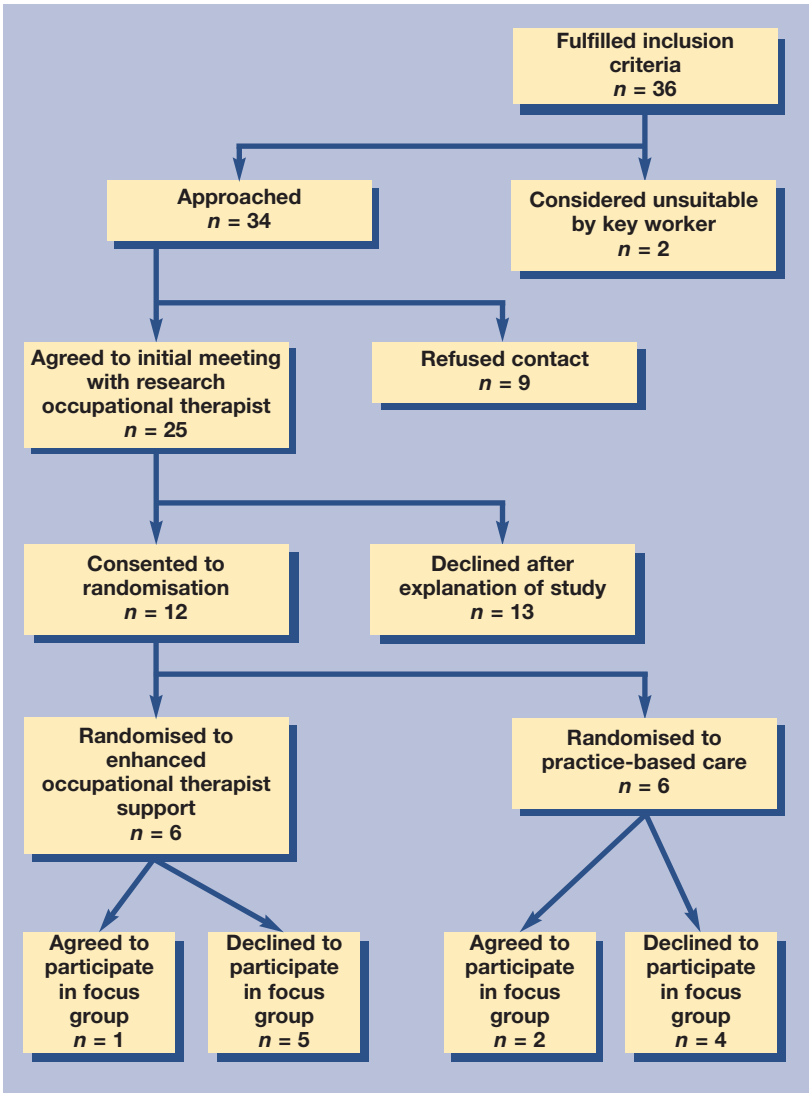

Figure 1. Recruitment and flow of participants through the study.

How this fits in

People with schizophrenia have an increased risk of morbidity and mortality from coronary heart disease. At least part of this elevated risk is due to lifestyle factors and barriers in accessing services designed to promote physical health. The lack of evidence for interventions designed to reduce coronary heart disease risk among people with schizophrenia is probably due to the inherent difficulties in recruitment to studies testing their effectiveness. Randomised controlled trials may not be the most suitable way to evaluate community-based interventions for people with schizophrenia.

both participants in the practice-based care group feeling that they had received an additional service in the baseline and follow-up visits.

DISCUSSION

The aim of this pilot study was to examine the feasibility of delivering an intervention designed to reduce the coronary heart disease risk among people with schizophrenia. Recruitment remained the greatest challenge for the research occupational therapist. There can be little doubt that the recruitment process acted as a form of intervention in itself. Ultimately, some subjects were reluctant to agree to participation for fear that they would lose contact with the research occupational therapist.

The reasons for participants' reticence to complete assessments of their mental state became clear in the focus group. Subjects felt that the psychiatric services already knew large amounts of their personal information and believed that their physical health bore no relationship to this aspect of their lives and should, therefore, be treated in a separate way.

This study has piloted a model of coronary heart disease health promotion, which utilises a mental health professional to deliver a custom-made health promotion package. It has sought to break down some of the barriers preventing people with severe and enduring mental health problems from partaking in activities to promote a healthier lifestyle. However, we may have underestimated the way that psychotic mental illness is likely to eclipse any concern about the future prevention of coronary heart disease.

This pilot study has demonstrated the difficulty of testing complex interventions among people with schizophrenia. The new General Medical Services contract requires practices to screen this group for coronary heart disease risk factors,[6] but shies away from setting targets in terms of improved outcomes. The challenge for service providers is to explore ways of engaging this group to deliver interventions aimed at improving their physical health. For researchers the challenge is to think creatively about how to test evaluations in a way that is acceptable to potential participants.

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Ethics committee

Nottingham City Hospital Research Ethics Committee (EC01/157)

Competing interests

None

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