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Challenges associated with recruiting multigenerational, multicultural families into a randomised controlled trial: Balancing feasibility with validity

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ABSTRACT

Recruitment of participants into research studies has become an increasingly difficult task with justifiable criticisms of representativeness of samples. The difficulties of recruitment are exacerbated when the study is longitudinal, requires multiple members from one family and incorporates people from non-dominant ethnic backgrounds.

This paper describes a complex trial's recruitment process. Family groups were required for a longitudinal randomised controlled trial investigating links between health and dietary behaviours with an aim to improve primary prevention health messages and initiatives. To be representative of the multi-ethnic composition of the South Australian population, families from three of South Australia's largest ethnic backgrounds were invited to participate. Of these, only families with participating members spanning three generations were enrolled, so that links between health and lifestyle behaviours with possible generational ties could be investigated.

Immense difficulties were faced during recruitment and significant modifications to the initial recruitment plan were necessary to enable the enrolment of 96 families. Challenges faced included lack of response to recruitment materials displaying complex eligibility criteria and different response outcomes from different communities. Solutions implemented included simplifying materials and tailoring recruitment activities to specific communities' needs.

This trial's recruitment journey will be used as a case study to highlight the practicalities of recruiting for complex trials. Recommendations will be provided for future researchers seeking to recruit multigenerational, multi-ethnic families into the same study, along with issues to consider regarding the implications of the recruitment journey on the integrity of a complex trial and the potential threats to internal validity.

1. Introduction

Recruitment of a representative sample of participants is an essential stage in a successful randomised clinical trial (RCT: [28]) because the subsequent data impacts not only on the interpretation and generalisability of results [3] but also on the potential to use findings in the development of public health initiatives or programmes [15]. The ideal recruitment phase is time-efficient, cost-effective and yields a sample representative of the targeted population [3].

Participant recruitment is, however, also one of the most challenging phases of a trial [6]; particularly recruitment from ethnic minority groups [5]. Many researchers have published their experiences, providing recruitment advice relevant to specific populations, in order to avoid repetition of the same recruitment problems (e.g., [8,16,30,32]). However, recommendations are lacking for optimal recruitment from different ethnic minority groups in Australia, as well as for the recruitment of multi-generational family units from different ethnic backgrounds into the same trial. Moreover, despite the growing focus on the challenges associated with recruitment from ethnic minority groups, under-representation remains a problem [15,16,31].

In an RCT involving the initial test of a novel intervention, care needs to be taken to manage threats to the internal validity of the trial, so that the efficacy of the intervention itself can be examined [29]. Recruiting all participants in similar and controlled ways can help to keep sample bias based on recruitment activity to a minimum. Conversely, in order to address low recruitment rates from ethnic minority groups, some researchers have recommended using multiple concurrent recruitment activities as the best approach for maximising recruitment opportunities while keeping time and cost low (e.g., [5,11,13,22]). Indeed, it has been noted that different populations respond to different recruitment calls [8,21,22], and this provides strong support for the implementation of multiple, and potentially divergent, recruitment activities to attract a demographically diverse sample. However, the implications of a multi-

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pronged recruitment approach on the integrity of trials have not been adequately addressed.

Using a recent randomised controlled trial that encountered significant recruitment challenges as a case study, this paper will discuss the discrepancy between an ideal recruitment plan and its real-life outcome when recruiting for a complex trial involving multigenerational, multiethnic family groups in a longitudinal, six month study. By documenting the recruitment journey's challenges and offering recommendations based on the trial's experience, it is hoped that future researchers seeking to work with these populations may avoid similar difficulties, and be able to make more informed selections of recruitment activities. In addition, by discussing the implications of the recruitment experience for the integrity of the current trial, issues may be raised for future researchers to consider at both the planning stage and when interpreting results.

2. Methods

2.1. Description of the trial

This longitudinal randomised controlled trial entitled 'Intergenerational transmission of dietary behaviour' set out to investigate the intergenerational transmission of eating and lifestyle behaviours in Australian families and whether both information transmission and behaviour could be influenced by provision of familial risk information for a number of lifestyle-related chronic illnesses (heart disease, diabetes, breast and colorectal cancer). It was anticipated that families from different ethnic communities, with different traditional eating habits and health profiles, might respond differently to these messages and that different family members may adopt the role of health "promoter". Following Ethics approval, families with Anglo, Italian or Vietnamese ethnic background were invited to participate in an effort to achieve a sample that represented three of Australia's largest ethnic groups [2]. Each has different traditional dietary habits, and represents different waves of immigration to Australia. A traditional Vietnamese diet (e.g., high levels of green leafy vegetables, fruits, lower levels of meats and little dairy) is considerably lower in fat and higher in fibre than the Western diet which is much higher in saturated fats and low fibre [17]. The Mediterranean diet (high levels of monounsaturated fats from olive oil, seafood, fruits, vegetables, grains) is typical of traditional Italian eating habits [34].

In relation to immigration, families with Vietnamese cultural background represent a more recent immigration wave from the 1970s and 1980s; families with Italian background characterise post-World War II immigration; and families with Anglo background represent earlier immigration. In addition to characterising different immigration patterns and eating habits, these three ethnic groups differ in incidence of overweight. In Australia, patterns of obesity and overweight in children have been linked to the sub-continental origins of their parents [4], with Italian-Australians having a higher incidence of overweight than the population average, whereas rates among Vietnamese-Australians are lower [23]. In addition, patterns of disease, such as cardiovascular disease, differ by birth country in Australia, with Vietnamese having the lowest incidence, followed by Italians and then those born in Australia [10]. In order to examine the intergenerational transmission of health behaviours, families with at least five participating members spanning three generations were to be recruited.

Prior to consenting to participate, each family was given information about the study and its likely time commitment. Those who did not believe that they had sufficient time to complete the study requirements could elect not to participate.

Each enrolled family consented to participate at two time points six months apart, pre-intervention and post-intervention. On both occasions, each family member completed an interview and a questionnaire. The structured interview assessed patterns of encouragement and discouragement of healthy (eating fruits, vegetables, foods high in fibre, physical exercise) and unhealthy behaviours (sedentary behaviours, eating snack foods, smoking (adults only) and alcohol consumption (adults only)) within the family social network. Participants were interviewed individually over the phone for approximately 15–20 min by a trained Clinical Psychologist (first author). The interviews were scheduled flexibly and conducted at any time that suited each participant. Most participants were at home at the time of the interview. Many of the adult and older adolescent participants were alone on the phone at the time of the interview, but younger children were often interviewed with a parent present, over speaker phone.

A questionnaire was completed at baseline (prior to the interview) and at 6-month follow-up. It was specifically designed for the study and incorporated a range of pre-existing, standardised measures as well as items devised specifically for the study. Participants were asked to answer questions related to demographic information, current eating and physical activity behaviour, eating and physical activity intentions, attitudes towards food and perceived disease risk, and those not born in Australia completed an acculturation scale. At baseline, the parent generation also provided detailed information of family morbidity of heart disease, diabetes, breast cancer and colorectal cancer spanning three generations. This family health history information formed the basis for the educational intervention component of the study (see Fig. 1). The questionnaires were completed individually by each participant, with children completing a short form which excluded questions about disease risk and health history. The questionnaires took approximately 20–30 min to complete and were sent to participants to complete at their convenience. Upon receipt of a family's completed questionnaires, the family was contacted to schedule interview times.

At enrolment, each family was randomly assigned to the intervention (receipt of personalised familial risk information and education three months post-baseline) or control condition (receipt of no information between the two time points). Following completion of each time point, the family received $50 shopping vouchers to share ($100 total by the end of the 6-month follow-up) as a reimbursement for their time. Families in the control condition received the intervention after the completion of the second time point.

2.2. Trial eligibility criteria

To obtain an adequate sample size for statistical power, 50 families in each cultural group were sought. This estimate was based on power analyses accounting for potential clustering of the outcome variables among family members using generalised linear modelling across the two time points. Enquiring callers were asked (1) "In which country(ies) were you and your parents born?" and (2) "Do you identify your family as Italian-Australian, Vietnamese-Australian or Anglo-Australian?" Callers' families were enrolled if they identified as having one of these ethnicities, if the parents and grandparents were born in Italy, Vietnam, Australia or another English-speaking country and the children were born in Australia. In addition, the eligibility required at least one of the children to be aged between 10 and 18 years and still living at home. This study was specifically interested in families with dependent children. Younger children were required to be aged within this range to enable competent completion of the questionnaire and interview, and those over 18 years were no longer considered as children. Furthermore, participating families were required to enrol at least five members with representation across three generations in order to capture the intergenerational influence of health behaviours through the family.

2.3. Recruitment

2.3.1. Initial approaches to recruitment (stage one)

The research team's collective experience in conducting clinical trials spanned more than 30 years. Based on their experience from