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Impact of informed consent content and length on recruitment of older adults into a community based primary prevention trial

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ABSTRACT

Aims: To compare recruitment, refusal and randomisation rates of older adults into a general practice-based clinical trial with two versions (varied format, content and language) of the Participant Information and Consent Form (PICF).

Methods: This prospective PICF study was conducted within the STAREE (STAtins in Reducing Events in the Elderly) clinical trial. Participants phone screened between October 2015 to February 2016 formed Group 1 and were mailed the extended PICF version and participants phone screened between October 2016 to February 2017 formed Group 2 and were mailed the shortened PICF version. Participants who attended a subsequent baseline screening visit were guided through a comprehensive informed consent process.

Results: During the screening phase of the trial, the likelihood of refusing trial participation was lower in Group 2 compared to Group 1 equating to an overall 23% reduction in risk (RR 0.77, P = 0.005, 95% CI 0.62–0.95). Group 2 had a 6.4% higher randomisation rate compared with Group 1 (65.3% versus 58.9% respectively) but this difference was not statistically significant. Factors associated with trial participation were male gender, age between 70 and 75 years and living alone (all $p < .0.05$).

Conclusions: Whilst avoiding lengthy and complex PICF documents may assist with initial trial engagement, it needs to be supplemented with other strategies to support ongoing trial interest to randomisation and beyond. Participants refused trial participation throughout the screening phase indicating that the PICF was only one factor among several affecting an individual's decision to participate in this clinical trial.

1. Background

To date, there has been an underrepresentation of older adults in clinical trials. Offering older adults the opportunity to participate in clinical research is paramount given that life expectancy and the proportion of older people living beyond their seventh decade is dramatically increasing. In Australia there are close to 4 million people aged 65 years and over, representing 15% of the population [1]. This is consistent with the global population total of 13%, which is expected to increase to more than 2 billion people by 2050 [2]. Thus there is a compelling argument for including older adults in clinical trials and establishing age-specific evidence to support best practice in the clinical and medical care of this population. Furthermore garnering data around the clinical efficacy and safety (or risks and benefits) of medical treatments in this age group is crucial as they represent a group that are among the highest medication users [3].

Despite the growing need for more clinical trial evidence in older populations, there are known barriers to recruiting older adults into clinical research studies. Recruitment barriers include difficulty locating willing older adults, access issues, ethnicity barriers, heightened personal fears or concerns about clinical research and other existing comorbidities that may exclude older adults from participating [4,5]. The informed consent process itself may also pose a potential barrier to trial participation. Specifically, how to best tailor the 'how much, when to and what sort' of information to provide to older research trial participants, allowing for variations in health literacy, education and age-related sensory (visual and aural) and cognitive changes is unclear [6,7].

The Participant Information and Consent Form (PICF) is one aspect of the informed consent process that can be a critical factor influencing willingness to participate in a clinical trial [7,8]. With respect to the PICF content and language, balancing the requirements of any local human research ethics committee with the needs of the potential research participants can be challenging. Ethically, potential participants

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must be given sufficient information to make an informed decision about trial participation and not simply opt into a research trial [9]. It has been suggested that if the PICF document is too long, features complex language and provides too much detailed information on the risks and benefits of participating, it may likely be perceived as confusing by the older adult population [6,10]. Some of the issues around misunderstanding of information may be mitigated if the PICF document is supported by an interactive opportunity to discuss its content [7,11]. This is positively viewed if, when interacting with older adults, there is an extended amount of time to read and review the document provided [5].

There is no gold standard for how the PICF should be presented and in most instances it is provided before a face to face discussion with the research team. This is the approach taken in the STAtins in Reducing Events in the Elderly (STAREE) trial, a general practice based, pragmatic, public health randomised control trial (RCT) exploring the potential impact of statin therapy on healthy ageing in adults 70 years of age and older (ClinicalTrials.gov Identifier: NCT0299123). As part of our process evaluation during the vanguard phase, we explored the factors influencing willingness to participate in the clinical trial. It was noted that 1 in 4 invited participants opt out of the study following a successful eligibility phone screen. After receiving the PICF in the mail (with their screening appointment confirmation letter), a significant number of people reported they were concerned about the large number of reported potential side effects of statin treatment.

As a result, the PICF was updated to present a more balanced view of the potential risks and benefits of statins. In addition to this, the format was altered and the content shortened in specific parts. By comparing two versions of the PICF, with varied format, content and language, we aimed to assess if a shorter and more concise version led to a difference in the number of participants who remain interested in taking part in our clinical trial and proceeding to randomisation.

2. Methods

This prospective cohort study was conducted through Monash University, School of Public Health and Preventive Medicine (Melbourne, Australia). Ethical approval was obtained from the local institutional research board (Monash University Human Research Ethics Committee, MUHREC) and the Royal College of General Practitioners (RACGP), and the study adhered to the tenets of the Declaration of Helsinki. The study formed part of process evaluation during the early period of participant recruitment of a larger RCT (ClinicalTrials.gov Identifier: NCT0299123).

2.1. Participants

Participants who had been invited to take part in the STAREE trial, a phase IV pragmatic and general practice-based RCT, were eligible to take part in the PICF-study. Given the increase in recruitment numbers as the study progressed and the potential impact of season on recruitment numbers [12], the same enrolment months were selected for group comparison. In addition, the PICF-study was conducted across two time periods reflecting the stages of the informed consent process evaluation. Potentially eligible participants for the STAREE trial were identified from their general practice clinical database, wherein their usual general practitioner (GP) then sent them an invitation letter with a trial summary information brochure, and a request to call the trial office if they were interested in participating. At the time of the call, potential participants were informed more about the key aspects of the trial and guided through a phone eligibility screening questionnaire comprising 12 questions including past/current history of cardiovascular disease, current/previous statin treatment, and current diagnosis of diabetes. Following a successful phone screening, an appointment was made to attend two baseline screening visits four weeks apart with a trained research nurse. These were designated Baseline Visit 1 (BV1) and Baseline Visit 2 (BV2).

Participants for this PICF-study were assigned to the intervention based on the date they were invited into the STAREE trial (see below). Purposive sampling was used and groups were unmatched.

2.2. Intervention

2.2.1. Group 1 = standard PICF (extended version)

Potential participants phone screened during October 2015 to February 2016 were allocated to Group 1 and were sent the extended version of the PICF (version 1.4) with their appointment confirmation letter in the mail 2–3 weeks prior to BV1. PICF v 1.4 had 9 pages presented in a single column of text and featured a complete list (476 words) of the potential risks, or side effects, of the trial therapy based on the Therapeutic Goods Association (TGA) Product Information sheet. Therefore, the list included the most common, uncommon and rare potential side effects. The most common potential side effects, affecting $\geq$1% of consumers, were listed under seven symptom categories and included gastrointestinal disorders such as diarrhoea. The uncommon potential side effects, affecting $\geq$0.1–1% of consumers, were listed under twelve symptom categories and included musculoskeletal disorders such as tenderness or pain (myopathy), and finally the rare potential side effects affecting $\geq$ 0.01% to $<$ 0.1% of consumers were listed under three symptom categories and included effects such as severe hypersensitivity/anaphylaxis. The potential benefits of statin therapy were not listed but rather a standard statement reporting that "participants may experience health benefits from being placed on study medication" and that if shown, this "may enable this treatment to be available to more people in the future". This version of the PICF was approved for distribution to trial participants by MUHREC and the RACCP ethics committee in September 2015.

2.2.2. Group 2 = condensed PICF (version 1.5)

Potential participants phone screened during October 2016 to February 2017 were allocated to Group 2 and were sent the shortened version of the PICF (version 1.5) with their appointment confirmation letter in the mail 2–3 weeks prior to BV1. PICF v 1.5 had 6 pages presented in two columns of text and featured additional information about the potential benefits of trial medication including a list of the known potential benefits (i.e. reduction in levels of cholesterol in the blood) and also those less certain supporting the need for more research (i.e. reduced risk of dementia) (54 words). In addition, PICF v1.5 had a simplified list of potential side effects with the prevalence percentages and 2–3 symptom examples for the most common, uncommon and rare divisions listed above (248 words). Both the potential benefits and risks of participating in the trial were listed in point form along with a note that the TGA Consumer Medicine sheet would be provided for more information with study medication. This version of the PICF was approved by MUHREC and the RACGP ethics committee in February 2016.

2.3. Consent process

Regardless of consent version, each participant presenting to BV1 was guided through a comprehensive informed consent process, adhering to The International Council for Harmonisation - Good Clinical Practice (ICH-GCP) guidelines, including a full and open discussion around all aspects of the clinical trial, answering any questions raised by the participant and getting the participant to repeat the key aspects of the trial. The informed consent process was undertaken in a private consulting room at the participant's primary general practice. Research staff were trained in GCP and effective communication including active listening skills, maintaining eye contact and speaking in a soft and welcoming manner.

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