

Patient retention gifts in clinical trials – undue inducement or justified motivational tools?

L J Burgess, N U Sulzer

The use of retention gifts in clinical trials has been controversial, with some ethicists maintaining that such gifts represent undue inducement to the trial participants. A study was conducted at TREAD Research, a site-managed organisation based at Tygerberg Hospital, in which 302 participants completed a questionnaire that focused on their opinion with regard to such gifts. The results

suggest that these gifts do not influence patients to participate in a clinical trial or influence them to remain on a trial should they wish to withdraw. However, they do act as a useful motivational tool and trial participants appreciate them.

S Afr Med J 2011;101:640-641.

To the Editor: Ethical controversy surrounds the issue of retention gifts in clinical trials and also the idea of remuneration for clinical trial participants. Some ethicists purport that retention gifts may influence a patient's decision to participate in a clinical trial, either by persuading them to participate in a trial or by resisting discontinuation against their better judgement. These gifts may therefore represent undue inducement, defined as 'the offer of an excessive, unwarranted, inappropriate or improper reward or other overture to obtain compliance'.¹ This may potentially compromise the informed consent process, the patient's health and the scientific validity of the trial, and is particularly relevant in a developing country such as South Africa, where vulnerable communities may be exploited.²⁻⁴ No guidance is provided on participant remuneration, when a gift may be undue, or what type of gift represents undue inducement in clinical trials.

Patient retention and keeping patients motivated in a clinical trial is a continuous process.⁵ Clinical trial participant drop-outs and those lost to follow-up after recruitment negatively affect study duration, cost and the generalising of study results, which may result in delaying a new agent's regulatory approval.⁶ High drop-out rates also pose a risk to the interpretation and validity of the research findings.⁶ It is significantly more expensive to recruit a patient onto a clinical trial than to retain a patient in the trial.⁵ Despite the impact such drop-outs and loss to follow-up may have on a clinical trial's final analysis, few pharmaceutical companies or clinical research organisations develop a formal retention plan with trial sites. For those that formulate such a plan, retention gifts often play an integral role, especially in long-term phase III trials.

Objectives

Our objectives were to study clinical trial participants' opinions on retention gifts and to ask patients to rate various retention gifts in order of preference.

Methods

This study was conducted by TREAD Research, a site-managed organisation based at Tygerberg Hospital, Western Cape, South

Africa, and approved by the Research Development and Support Department of Stellenbosch University. Candidates were recruited from current trials conducted at the trial site, and written informed consent was obtained from all participants in their home language before asking them to complete the questionnaire in their home language. This comprised five questions requiring a 'yes' or 'no' answer. A sixth question asked patients to rate nine retention gifts in order of preference and to suggest additional retention gifts that they might find useful. All data were entered into an Excel spreadsheet and analysed using descriptive statistics.

Results

A total of 302 questionnaires were completed by voluntary participants. Fig. 1 presents the responses to questions 1 - 4 of the questionnaire.

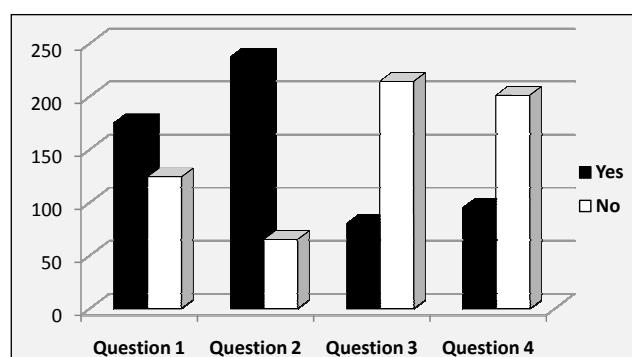


Fig. 1. Participants' responses to the questions: 1. Would the receipt of a retention gift during a trial of long duration influence you to remain on the study? 2. Would the receipt of a gift cause you to tell others about clinical trials and the benefits of taking part in a trial? 3. If you knew before you signed consent that you were going to receive a gift, would this influence your decision to take part? 4. Would the fact that you are to receive a gift persuade you to stay on the study even if you wanted to withdraw from the trial?

Of the 302 respondents, 126 (41.7%) had previously received a retention gift. Of these, 64.3% said that the receipt of a gift did not influence them to stay on the trial and 69.0% responded that the quality of the gift did not affect their participation.

Fig. 2 presents the participants' ratings of the retention gifts. The most popular retention gift was a recipe book, followed by a cooler bag, an umbrella and a fleecy blanket. Suggestions for other gifts included a clock, a glucometer, a calculator and a key holder.

TREAD Research/Cardiology Unit, Department of Internal Medicine, Tygerberg Hospital and Stellenbosch University, Tygerberg, W Cape

L J Burgess, MB ChB, MMed (Chem Path), PhD, Postgrad Dip Int Research Ethics
N U Sulzer, BSc (Med) (Hons), MSc (Med)

Corresponding author: L J Burgess (Lesley@treadresearch.com)

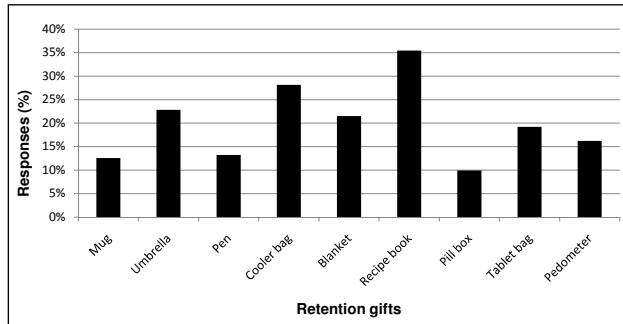


Fig. 2. Participants' ratings of retention gifts.

Discussion

Our results suggest that, in this setting, the receipt of retention gifts does *not* influence patients to participate in a clinical trial or influence them to remain on a trial should they wish to withdraw. However, these gifts act as a useful motivational tool for studies of long duration, and trial participants appreciate them.⁷

A study of patients' motivations for participating in a trial⁷ reported that access to medical care and making a contribution to scientific knowledge are common motivations for participation in cardiovascular clinical trials and that the role of remuneration is relatively unimportant. This sentiment is reflected in our findings regarding retention gifts. Most participants responded that receiving a retention gift would not influence their decision to participate in a clinical trial or influence them to remain on a trial should they wish to withdraw.

However, our results suggest that retention gifts in this setting function as a motivational tool and are appreciated by trial participants. Most respondents indicated that the receipt of such a gift would influence them to remain on a study and that they would share this fact with others. Most studies conducted at this trial unit are long-term, phase III cardiovascular trials where patients often remain on a single study for up to 5 years. The receipt of a retention gift, which is often useful (e.g. a blanket or cooler bag) or educational

(e.g. a recipe book or pedometer), functions as a critical motivational tool for participants. Understanding the underlying motivators for each patient is the first step to ensuring that their study expectations are met.⁵

Of the 302 respondents, 126 (41.7%) had previously received a retention gift. Of these, 64.3% said that the receipt of a gift did not influence them to stay on the trial and 69.0% responded that the quality of the gift did not affect their participation. This is despite a study at this same trial site showing that the median (1st, 3rd quartile) reported hourly income of study participants was R10.23 (R4.10, R29.54).⁸

Conclusions

Generalisations regarding retention gifts for clinical trial participation are impossible. A 'one size fits all' approach to payment of trial participants is arguably injudicious,⁹ as is such an approach to providing retention gifts. Implemented and used appropriately in the correct setting, these gifts are useful motivational tools to retain patients on long-term clinical trials where minimising drop-out and lost-to-follow-up rates is imperative to ensure statistical validity and clinical applicability of the trial's results.

References

1. The National Commission for the Protection of Human Subjects of Research. The Belmont Report. 1979. <http://ohsr.od.nih.gov/guidelines/belmont.html> (accessed 4 August 2011).
2. Moodley K, Myer L. Participant remuneration for research – how much is enough? *S Afr Med J* 2003;93(9):677-678.
3. Medical Research Council of South Africa. Guidelines on Ethics for Medical Research: General Principles. 4th ed. Tygerberg, W Cape: MRC, 2002.
4. Emanuel EJ, Currie XE, Herman A. Undue inducement in clinical research in developing countries: is it a worry? *Lancet* 2005;366:336-340.
5. Williams K, Hook-Seid N. Tried and true techniques for motivating and retaining patients in clinical trials. *MedicGlobal*, 2008. <http://medicglobal.com> (accessed 24 February 2010).
6. Betz D, Betz D, Leahy D. Burden of patient dropouts and patients lost-to-follow-up on clinical studies. <http://lost-to-follow-up.com> (accessed 17 February 2010).
7. Burgess LJ Sulzer NU, Hoosain F, et al. Patients' motivations for participating in cardiovascular clinical trials: a local perspective. *CVJA* 2009;20:220-223.
8. Burgess LJ, Sulzer NU, Emanuel S. Clinical trial remuneration: the patients' perspective. *S Afr Med J* 2008;98(2):95-97.
9. Horn L. Payment of clinical trial participants. *S Afr Med J* 2008;98(2):93-94.

Accepted 9 May 2011.