

# Presenting the results of clinical trials to participants

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## Introduction

Participants in clinical trials give their time and undergo procedures in the hope that they will obtain benefit for themselves and that they will be contributing to the advancement of medical science.<sup>1</sup> Traditionally little emphasis has been placed on informing participants of trial results, however, in the era of patient-centred care it is becoming increasingly recognised that researchers should involve participants to a greater extent in the design and operation of trials and take the time and effort to share the results appropriately. In addition, funding bodies and ethical committees now often ask for information on how participants will be informed of results adding further need to address this important issue. It has even been suggested that opportunities for disseminating results form part of the informed consent process.<sup>2</sup> The aim of this article is to highlight the need for researchers to communicate their results to study participants. Information was retrospectively collected from clinical centres who held a coffee morning to disseminate the one-year results from the three-year Treat to Target in Type 2 Diabetes (4-T) Trial (Current Controlled Trials number, ISRCTN 51125379).<sup>3</sup> Following a discussion of the results, suggestions for how the information collected could be used to inform further work in this area are made.

## Public understanding of science

There is current academic and political interest in the communication of science-related issues to the general public. However, in the general population science as a discipline remains poorly understood. It is reported that only 25% of the European and American public are 'scientifically literate' and there is a growing tendency for the public, particularly in the West to express scepticism of 'science'.<sup>4–6</sup> Scientists and researchers have a responsibility to publicise and promote their work in language that is easily understood. Routinely, participants in clinical trials are not given results unless their future care is affected.<sup>7</sup>

## Experience

In light of this it was decided to review how the one-year results from the 4-T Trial were published and subsequently discussed with participants. This open-label, multi-centre

trial allocated 708 participants with type 2 diabetes at random to the addition of a basal, biphasic or prandial insulin regimen to suboptimal oral antihyperglycaemic therapy (glycated haemoglobin (HbA<sub>1c</sub>) 7.0–10.0%). The one-year results, which were reported in September 2007,<sup>3</sup> concluded that a single analogue-insulin formulation added to metformin and sulfonylurea resulted in an HbA<sub>1c</sub> of 6.5% or less in a minority of participants. The addition of biphasic or prandial insulin aspart reduced levels more than the addition of basal insulin detemir, but were associated with greater risks of hypoglycaemia and weight gain.<sup>3</sup>

On the day the results were presented and published,<sup>3</sup> a press release was emailed to all clinical centres highlighting the main findings. Centres were requested to forward a printed copy of this press release to all their participants immediately. In addition the 4-T Steering Committee had agreed previously that there should be an informal opportunity to share the results in detail with participants. While ethical committees take a favourable view on those willing to take the time to explain the results to their participants there is no consensus for a preferred format.<sup>2</sup> All 4-T clinical centres were encouraged to organise an informal gathering or coffee morning. Centres were asked to report back to the 4-T coordinating centre in Oxford with information about their coffee morning, including reasons for organising one, or not. One centre also provided anonymised comments from participants. This information was then collated and reviewed.

## The coffee mornings

Eight of the 58 4-T clinical centres across the UK and Ireland chose to host coffee mornings. These were funded by Novo Nordisk Ltd at an average cost of £5 per person. In total 140 people attended, comprising about 70% of participants from the eight centres' original randomised total and nearly 20% of the trial population.

The format of these mornings differed across sites. One centre booked a conference room in a local hotel with catering for a light lunch. Most centres chose to hold a specific 4-T coffee morning in their own clinic setting during which the doctors and nurses were able to use a slide set prepared by the coordinating centre to present the results of the first year and explain what they might mean for participants in each arm of the trial.<sup>8</sup>

Some sites decided not to arrange a coffee morning. A primary concern was that participants were unwilling to discuss their diabetes and treatment with strangers from the same local area. Other centres have a majority of working age participants and this would have necessitated additional time off

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work for them. Other concerns included elderly patients travelling to attend an additional visit and presenting results in English to individuals who do not have English as their first language. Most centres chose to discuss the results with each participant individually during their scheduled clinic visits although some admitted to only discussing the results if they 'had time'.

## Discussion

It is easy to underestimate the importance of the trial participant when considering the wider benefits of medical research but recruitment and retention of individuals is at the heart of every clinical trial. A relatively low-cost event, the coffee morning, has been shown to be a positive initiative, and anecdotal evidence suggests that participants have agreed to take part in subsequent trials as a direct result of their experience.

Direct feedback from participants themselves clearly demonstrated the level of appreciation they felt. There was no evidence to support the argument that participants were not interested in receiving the results at all.<sup>2</sup> Participants at each site will not necessarily be of a similar age/gender/background. This may limit the success of a social event, particularly if participant numbers are low.

It is important to be aware of issues that are important to participants. From feedback received it is apparent that the majority of patient queries centred around weight gain associated with insulin therapy. Although the 4-T Trial has a number of questionnaires which enable formal analysis of quality of life, additional 'unstructured' comments received in an informal setting offer insight and understanding to the realities of living with chronic conditions such as type 2 diabetes.

The 4-T method of providing interim trial results to participants was positively received by both participants and clinical centres and shows promise as a method of disseminating information.

Further research is needed to assess participant views on the content and setting of such events both during trials and once final results have been published. Within 4-T, there are plans to encourage all sites to hold end of trial coffee mornings or similar events to facilitate the dissemination of the final 4-T results.

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