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Reactions of participants to the results of a randomised controlled trial: exploratory study

Claire Snowdon, Jo Garcia, Diana Elbourne

Abstract

Objectives: To assess views of parents of babies who participated in a neonatal trial, about feedback of trial results.

Design: Qualitative analysis of interviews.

Setting: Parents' homes.

Subjects: Parents of 24 surviving babies enrolled in a UK randomised controlled trial comparing ventilatory support by extracorporeal membrane oxygenation with conventional management.

Main outcome measures: Views about contents of results, reactions to results, effect of hindsight, and importance of feedback.

Results: Information about mortality was well understood by the parents but morbidity was less clearly reported. Even when the content was emotionally exacting, the information was still wanted as it removed uncertainty; provided an endpoint to difficult events; promoted further discussion within couples; and acknowledged their contribution to answering an important clinical question.

Conclusions: Feedback of trial results to participants should be a consideration of researchers, but a careful approach is required. This study was based on a highly selective group of parents within a particularly sensitive trial. More research is needed to assess the extent to which these results can be generalised to other trials or to groups such as bereaved parents.

Introduction

In recent years there has been a demand for the feedback of results of medical research to participants.[1–5] There are, however, practical and ethical factors to consider as results can be complicated, alarming, and distressing. Two studies examined participants' responses to results in sensitive situations where the results could induce feelings of guilt or fear.[6 7]

Epidemiological research into risk factors for paediatric brain tumours indicated an association with parental behaviour or lifestyle, or both.[6] Despite concerns about the impact on parents a questionnaire based study showed that mothers said that they understood the results and viewed feedback as important. The authors concluded that feedback was not emotionally exacting, but a poor response rate undermined the validity of their findings.

When treatment is randomised feedback may be particularly problematic. While randomisation is appropriate at the start of a trial at closure uncertainty should (ideally) be resolved. Trial participants who did not receive what was shown to be the best treatment may with hindsight feel deprived or placed at risk. In a trial of surgery to lower cholesterol after myocardial infarction, where mortality was higher in the control group, a quality of life assessment showed no detrimental effects of feedback.[7]

Although these studies suggest that feedback of sensitive results is not problematic closer examination is needed. Our study describes the reactions of a sample of parents of surviving babies to the communication of results of a neonatal trial.

United Kingdom collaborative trial of extracorporeal membrane oxygenation

The trial compared two methods of ventilatory support for critically ill neonates with acute respiratory failure. At randomisation the babies were already receiving ventilatory support by conventional management in a neonatal intensive care unit. Conventional management was compared with oxygenation of the blood by an external circuit (extracorporeal membrane oxygenation) in one of five specialist centres. Neonatal extracorporeal membrane oxygenation was only available in the trial as it was an unevaluated treatment.

The trial showed that extracorporeal membrane oxygenation reduces the risk of early death; 30 of 93 babies allocated to extracorporeal membrane oxygenation died compared with 54 of 92 babies allocated to conventional management.[8] Only one baby in each treatment group was found to have a severe disability at 1 year old.[9]

Medical Statistics Unit, London School of Hygiene and Tropical Medicine, University of London, London WC1E 7HT

Claire Snowdon, *research fellow*

Diana Elbourne, *senior lecturer*

National Perinatal Epidemiology Unit, University of Oxford, Radcliffe Infirmary, Oxford OX2 6HE

Jo Garcia, *social scientist*

Correspondence to: Ms C Snowdon, Centre for Family Research, University of Cambridge, Cambridge CB2 3RF
CMS1000@cam.ac.uk

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The boxes show how the results were communicated to the parents.

Subjects and methods

Study design

Eight parents (seven mothers and one father) of seven babies in the trial participated in a pilot study by telephone (table 1). These parents had already taken part in a general study of parental views of the trial.[10] As a result of the pilot study minor modifications were made to the questions.

Owing to the constraints of time and funding it was not possible to invite all parents who received the results to join the main study. Starting with the most recently recruited participants small groups were contacted by letter and asked to indicate on a form whether they would like to participate. This process continued until 20 interviews were achieved. The only selection criteria were that a member of the trial team who knew the family circumstances had no objection to contact with the parents and, for practical reasons, that English was the parents' first language. The parents of 33 babies were contacted; in 20 cases parents agreed to participate, five refused, and eight did not respond (response rate 61%).

The pilot study interviews were carried out by telephone (n = 8). This figure includes six women and one couple, all interviewed separately. Main study interviews were carried out in the parents' homes (n = 19) or by telephone (n = 1). Both parents were present during all home interviews. For the telephone interview the parents owned two telephones, and so it was possible to carry out a joint interview. Three cases were excluded after interview; the parents of two babies allocated to conventional management and one to extracorporeal membrane oxygenation stated that they had not received the results despite our understanding to the contrary from earlier contact.

A sample of 24 women and 18 men (the parents of 24 babies) was obtained from the pilot and main study. Table 2 shows the parents' characteristics.

The transcribed interviews were analysed using the ATLAS–TI computer package.[11]

The trial results were discussed during the interview only after the parents had described their experiences. This enabled the interviewer to gain information about the parents' circumstances and opinions and to develop a relationship with the parents; the results could also be placed in the context of the sequence of events after the babies' delivery.

Communication of results to the parents

At an early stage the steering committee decided that all the parents of babies enrolled in the trial would be offered the results. The process differed according to whether the baby survived. Four months after birth the parents of 95 surviving babies were sent a questionnaire about their experiences. The questionnaire included a box for the parents to tick if they wanted the results of the trial. The parents of six babies were not sent the questionnaire: in four cases the child was still in hospital, one couple were unable to read, and another couple wanted no further contact. Questionnaires were returned by the parents of 71 surviving babies (75%); all requested a copy of the findings. The response rate does not measure the level of interest in the results as non-responders may have been unaware of the role of the questionnaire in accessing the trial results.

If parents were bereaved their paediatrician was sent a copy of the proposed letter to the parents and asked if contact was appropriate. The paediatricians for 81 babies were approached and contact was approved in 68 cases (84%). The parents were contacted (with the exception of one family who did not speak English) and asked if they would like to complete the questionnaire (by post, telephone, or direct contact). They were also asked if they wanted to see the results of the trial. Of 67 sets of parents, 38 (57%) responded; 34 requested the results, three declined, and in one case the preference was unclear. Two letters were returned by the post office.

In February 1996 the trial results were sent to the parents. Three versions of the letter were devised and sent to the parents according to their baby's outcome: survivors; those treated by extracorporeal membrane oxygenation who died; those treated conventionally who died. The accompanying box contains an extract from the letter to parents of surviving babies. It later emerged that some parents had not received the results. All parents of surviving babies who had requested the results were telephoned to check whether they had arrived. A second mailing took place at variable times in 1997 as each case of missing results emerged. This procedure was not adopted comprehensively for the bereaved parents because of the uncertainty about the benefits of checking whether the results had been received against the potential for causing distress.

This paper concentrates on feedback of trial results to parents of surviving babies.

Extract from letter to parents of surviving babies

In brief, babies randomised to ECMO were more likely to leave hospital alive than babies randomised to conventional management on a ventilator. All children in the trial over 1 year of age have been seen by a research paediatrician; most of the children are fine, but a few have problems. The chances of having problems are roughly the same, whether the children had ECMO or conventional management as babies.

In the light of these findings, recruitment to the trial has been stopped, with the recommendation that ECMO support be considered for certain severely ill babies with respiratory failure. It is because of your decision to enter [baby's name] into the trial that we have been able to find out that ECMO in some circumstances is such a valuable treatment. Thank you.

Results

Content

Before discussing the letter giving the results of the trial the parents were asked if they had thought about what the trial would show. In nine of the 14 interviews with parents of babies allocated to extracorporeal membrane oxygenation the parents said they thought that the treatment their baby received would be the better treatment. Although their views were based mainly on personal experience other reasons included confidence in the medical staff and knowledge of the use of this approach in the United States. Their babies

survived and they attributed this to extracorporeal membrane oxygenation. One couple, Rose and Liam, drew the same conclusion although for different reasons. Their son had complications with his treatment, and at times Rose believed he was suffering because of their decision to include him in the trial. She thought extracorporeal membrane oxygenation a difficult and risky treatment, justified only by its success.

In three interviews the parents of babies treated conventionally said they had thought extracorporeal membrane oxygenation would be the better treatment. Neil commented:

"They [the researchers] must be pretty sure that it may come out on top in the fact that they are prepared to have a trial on it. I mean if it was like a no no from the beginning they wouldn't even have got that far, so there must have been some school of thought that was suggesting that it may be a better form of treatment and it was just like a—I don't know—a way of making sure before going straight into it."

In four interviews the parents of babies who were treated conventionally had thought that conventional management would be the better treatment. When they received the results they were "surprised" (Lorna, Helen, and Bill) and "quite shocked" (Gail), mostly because their babies had survived. Janet was the only parent who thought this treatment would be the more effective because "they had used [conventional management] for a long time now."

In 23 of the 24 interviews at least one parent correctly described improved rates of survival or said that extracorporeal membrane oxygenation was shown to be the better treatment. The similarity in health status of the surviving babies in both groups at one year was less clearly described, with parents in only four interviews accurately stating there were no major differences. In eight interviews the parents thought that the babies treated conventionally had more problems than those treated by extracorporeal membrane oxygenation. In three interviews parents stated that there were more side effects from extracorporeal membrane oxygenation. Eileen said:

"It was quite a shock to find out how many disabilities you can get from ECMO."

Table 1 Parents interviewed for study (names are pseudonyms)

Treatment group	
Extracorporeal membrane oxygenation	**Conventional management**
Emma and Russell	Gail and Bill
Eileen and Jerry	Hilary and John
Melanie and Lee	Valerie and Jim
Anna and Eric	Jo and Frank
Julie and Martin	Shirley and Hugh
Sophie and Ray	Moira and Dan
Penny and Duncan	Lorna and Neil*
Liz and Carl	Janet*
Rose and Liam†	Helen*
Ellen and Adam	Sandra*
Tina and Doug	
Mary*	
Andrea*	
Angela*	
14 interviews (11 joint, 3 telephone (pilot))	11 interviews (6 joint, 5 telephone (pilot))

*Interviewed for pilot study.
†Telephone interview for main study.

Table 2 Characteristics of parents in study

Variable	Value
Maternal age (years) (mean; range)	31 (25-41)
Paternal age (years) (mean; range)	34 (28-48)
Age of child (weeks) (median; range)	121 (69-234)
Disability status at 1 year of age:	
Severe	0
Signs of impairment or disability	5
Signs of impairment without disability	2
No signs of impairment or disability	17
Random allocation to:	
Extracorporeal membrane oxygenation (received)	12
Extracorporeal membrane oxygenation (received conventional management)	2
Conventional management	10

Level of information

It is difficult to pitch information at a level suitable for everyone. While some parents found it difficult to understand the letter others thought it "wasn't enough" (Adam) and was "sketchy" (Lee), and some wanted more information. Bill and Frank wanted to see "graphs" and "figures." Ellen and Adam, Shirley and Hugh, and Rose and Liam had sought further details through published material.[8] Rose said:

"I wanted more information (as much as I could get) and I really wanted to find out more about the outcomes, for kids specifically with the condition that Callum had."

Reactions to results

Pleasure

Six women described the pleasure they felt on reading the results. They were "over the moon" (Liz), "pleased" (Julie and Sandra), "very pleased" (Tina and Mary), and "glad" (Hilary). They felt a great personal involvement in the trial, and there was a sense of having made an important contribution. Hilary took pleasure in being "part of helping other children have the benefit of getting the best treatment that was possible." Hilary and Liz expressed relief that the trial had come to an early close, ending the trial situation for parents and establishing extracorporeal membrane oxygenation as an established treatment.

Feeling lucky

The parents of babies who were treated conventionally could find the information that babies in this treatment group were less likely to survive "rather sobering." In eight of 14 interviews the parents repeatedly described themselves as lucky. The results emphasised how different things might have been:

"Statistically she shouldn't be here, and there's no doubt about that … when we picked it up and examined the statistics it was—it was a shock to realise that … she had no real—real sort of chance. So it was a miracle." (Bill)

Feeling lucky was not limited to parents of babies who were treated conventionally as the thought that their baby's life depended on a random process could be generally disconcerting. Tina felt they were fortunate to be in the right place at the right time:

"It's not so much we were lucky to get ECMO because we were taking part in the trial. We were lucky to be able to take part in that trial! The crazy thing is that if the hospital Freddy has been born in [wasn't] in

the trial, there would have been this life saving treatment that we would never even have heard of."

Eileen and Jerry, Rose, and Andrea felt lucky that their baby was unaffected by the side effects they thought were associated with extracorporeal membrane oxygenation.

Feeling upset

A major concern in feeding back results to participants is that the content may be distressing or alarming. In 10 interviews (parents of four babies treated by extracorporeal membrane oxygenation and six conventionally) parents described degrees of upset. Some were "shocked" (Sophie, Eileen, Liam, Bill, and Jim). Hilary said it was "quite upsetting" and "shook us up." John said "it brought it all back to us again." The results "bothered" Moira, Lorna was "a bit down," and Valerie was upset by the reference to the babies who had died. Although the letter pointed out how few health problems there were among surviving babies in both treatment groups, Eileen worried about her son's current and future health:

"When we got them and we read about how many disabilities there were, I then panicked about Joshua's eye sight, was his hearing okay, were his lungs working? And I phoned up the consultant and I had to go down there—just for peace of mind."

In eight interviews parents of babies treated conventionally said their child had had less chance of survival. Lorna said:

"I was a bit down, actually thinking he had the poorer of the two. You know I was thinking, oh it could have been a lot different. We were lucky that he managed on that type of treatment when the ECMO was probably—would probably have been a better course of treatment."

Shirley, like Ellen and Adam, said she was upset not for herself but for others:

"They're saying that ECMO worked and all the rest of it, and quite a high percentage survived. But if you sit there and you count how many children actually did die—I find it very upsetting for the parents."

Ellen and Adam sought further information from a published paper.[8] The letter had not worried them but they were upset by the paper:

Adam: "That was … the only time that actually I think since being at the hospital that that actually hit home again."

Ellen: "Yeah."

Interviewer: "Would you have preferred not to have had that information then?"

Ellen: "No."

Adam: "No. We prefer to have as much information as we can get."

Parents often said they believed they would have viewed the results differently if their child had had a poor outcome. Jo and Frank's son has long term complications. Although they did not say the results were upsetting Frank regretted not insisting on extracorporeal membrane oxygenation for his child. He knew that he could not have changed the allocation but still thought he should have "fought tooth and nail."

Effect of hindsight

Few parents said the results had affected their view of the trial, randomisation, their decision, or their doctor. Although some parents suggested that randomisation seemed unfair there was also recognition of the difficulties where there is uncertainty over treatment. Tina was aware of the need for the trial but saddened by the process. Liam and Angela expressed similar opinions:

"It's wrong to force every baby on every treatment because you don't know the outcome. Somewhere somebody's got to make an evaluation of that, but it's difficult to rationalise that other children were, in many respects, just denied that because of [a] spinning of the wheel." (Liam)

"I heard of a little boy … on the trial … and had been given conventional treament and he had died. I realise there has to be a trial, but it seems so terribly sad that he was one of the ones that had to be the statistic to prove it. It seems very sort of cold to actually deny some children the treatment." (Angela)

In an earlier interview Lorna said that she found randomisation helpful as it removed the responsibility of choosing treatment from herself and her husband. However, once extracorporeal membrane oxygenation was known to be the more effective treatment she viewed randomisation less positively:

"Two parents have got to live with that for the rest of their lives, thinking it was just all part of an experiment—obviously a … needed experiment etc, but if ECMO would have saved the baby, then—well, there's just no—what's the word I'm looking for? No, no justification for the trial."

Neil still thought that randomisation was helpful, and took a philosophical approach:

"His recovery was obviously delayed by the treatment he had [but if] he had had to move, something could have happened while he was being moved from hospital to hospital. So there's no guarantee that even if he had ended up having ECMO that everything would have turned out all right."

Importance of the results

Sending the results to parents informed them of the findings and, as recommended by the Royal College of Physicians,[12] acknowledged and thanked them for their help. It was clear that the parents felt strongly they should be sent the trial results out of courtesy and for further information. Bill described "a need to know" and Andrea thought it would be "unfair" if parents were not told the outcome. The results were important to Angela as they confirmed she was right in wanting extracorporeal membrane oxygenation for her son:

"You can feel like you are in limbo. You think you know something … but until you actually get the confirmation you don't feel completely sure of what—it's almost as if you don't know what you think you know, and then when you get the confirmation it's yes! yes! I feel more sure about myself now. Yes, I was right. All my instincts were right."

Jim saw the information as important, even if it was emotionally difficult news, drawing on the enormity of the parents' part in the process:

"If you're asking somebody to take part in a trial, there's no point sort of holding the hard facts back from anybody. If you're wanting people to put other people's lives in their hands … you've got to come back with figures and say: 'Look, this one was better than

that one' … if we'd nae gotten them I think we'd be quite, sort of, annoyed."

Although the chance to contribute to research was not the main reason for most parents participating, it was highly valued by some parents. There was often a sense of personal investment in the trial, and the letter made parents feel "included" (Julie), "important" (Lorna) and "part of it" (Mary). Sophie pointed out that as she and Ray had been involved in the trial for three years she wanted to know the results "otherwise how do you know you've been of any use."

Only Frank questioned why he had requested the results. He thought he had not taken the decision seriously and had simply ticked a box on the questionnaire. He said: "Don't know why I said send them … cos there's nothing I can do with them." His wife, Jo, thought the results would have some value and interest for their child at a later stage. This was a commonly held view. For most of the parents the letter was part of a collection of mementos of their baby's traumatic start to life. The results also marked the end of a stressful period.

Discussion

The parents in this study thought that the participants of a trial should have access to its results. For these parents the letter giving the results had been important for reasons in addition to providing information: it recalled an emotional time, sometimes prompting them to re-examine and discuss their experiences; it provided tangible information on a previously uncertain situation and clarified and rounded off a stressful period; and it acknowledged the important and valuable contribution they had made in answering a medical question.

The parents were surprised that results are not commonly sent to participants. They had often wanted more details about the trial and at the end of the interviews had frequently asked how the other parents felt. Some parents took the time to read a clinical paper[8]; protecting the parents from potentially distressing knowledge would have seemed paternalistic and possibly insulting. Although some parents were upset all reiterated that they wanted to know the results; they emphasised the need for a careful approach to communication of this information.

The results from this trial are particularly sensitive, and feedback was discussed with the steering group, an advisory meeting of voluntary groups, and the trial and study team. Of particular concern was the possible impact on bereaved parents especially when babies were treated conventionally. The original study was designed to include bereaved parents. When it became apparent that not all parents who requested results had received them a dilemma arose. Telephoning these parents to ask about receipt of results seemed insensitive, and there was concern that even a carefully worded letter might cause distress. It was therefore decided to contact only the parents of surviving babies. For future studies it is important to establish in advance the procedures for contacting vulnerable groups.

It should not, however, be assumed that bereaved parents would have only viewed the results negatively. Firstly, these parents would have chosen to see the findings and, like the parents of surviving babies, may have used the results to talk to their families, or may have found relief in a resolution to their uncertainty over treatment. Secondly, these parents may have valued the contribution their baby made to the welfare of future families. Mary, a parent of one of the surviving children, was clear that when her family agreed to join the trial part of the decision was to make sense of their loss if their child died.

Key messages

- Feedback of results of randomised controlled trials can be part of an open and inclusive approach to participation in medical research
- The procedure for offering feedback should be considered at the start of a trial
- Results should only be sent to people who respond positively to such an offer, and particular attention paid to feedback to potentially vulnerable groups
- The effect of feedback of sensitive information needs evaluation in a variety of contexts

We suggest a cautious approach to feedback even in seemingly harmless circumstances. Only a few parents appreciated the news that there were few lasting effects of either treatment for survivors. Instead some parents felt that surviving children who were treated conventionally were at a disadvantage, and others that extracorporeal membrane oxygenation had worrying side effects.

It is crucial that only participants opting to receive the results of a trial are contacted. Although all the parents of surviving babies who returned their initial postal questionnaire chose to receive the results, three of the 38 bereaved parents who replied specifically did not want this information. It is clearly important that participants do not receive results without their permission. It could be argued that those who request results cannot know what they are agreeing to at the time; it is only when information is obtained that it is possible to say whether it is helpful or harmful. For this reason it is important that more research, especially with vulnerable groups, should be carried out.

Conclusions

As this study included only those parents who requested results this research was unlikely to show many parents who saw the results as irrelevant or unimportant. It may, however, have highlighted confusion and distress, and largely this was not the case.

There are limitations to the generalisability of this study. Firstly, we focused on the parents of babies who survived and, secondly, the study was conducted within the context of a single trial. It does, however, provide insights into the way trial results can be viewed and the different needs they can serve. A greater appreciation of the perspectives of trial participants may ease the experience of trial participation; it may also encourage a more open and egalitarian relationship between researchers and trial participants.

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Efficacy of home sampling for screening of *Chlamydia trachomatis*: randomised study

Lars Østergaard, Berit Andersen, Frede Olesen, Jens K Møller

Department of Infectious Diseases, Aarhus University Hospital, PP Ørumsgade 11, DK-8000 Aarhus C, Denmark
Lars Østergaard, *senior registrar*
Research Unit for General Practice, University of Aarhus, DK-8000 Aarhus C, Denmark
Berit Andersen, *research assistant*
Frede Olesen, *consultant physician*
Department of Clinical Microbiology, Aarhus University Hospital
Jens K Møller, *director*
Correspondence to: Dr Østergaard segalt@dadlnet.dk

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Urogenital infections caused by *Chlamydia trachomatis* are common and may cause female infertility and ectopic pregnancy. Such infections are treatable but as *C trachomatis* often causes no symptoms they may remain undetected. As screening for *C trachomatis* reduces the number of complications,[1] and self reportable screening criteria seem to have a low predictive value for infection,[2] testing people not seeking medical care seems relevant. *C trachomatis* can be detected by amplification of DNA from urine and vaginal secretions—samples that can be obtained at home and mailed directly to the laboratory.[3 4] Usually a swab sample is taken by a doctor but if a patient can collect a sample at home this may result in improved screening rates and thus more infections being detected.

Subjects, methods, and results

We randomised all 17 high schools in Aarhus County into two screening groups. In the home sampling group the females were asked to collect two urine samples and one vaginal flush sample[3] and the males were asked to collect one first void urine sample. These samples were mailed directly from home to the microbiology department at Aarhus University Hospital. In the usual testing (control) group the students were offered testing at their doctors or at the local clinic for sexually transmitted diseases. Both groups received a questionnaire and information on *C trachomatis* infection. The students were asked for their identification number, from which the number of infected respondents in the control group was calculated.

Students in the home sampling group were asked to give an address for receipt of the test results or the address of their doctor. To ensure that infected students followed our advice to seek treatment they were asked to give their doctor an envelope that contained a slip to be returned.

Students who returned the questionnaire were designated responders, and sexually experienced responders were called eligible responders. The efficacy measures were the number of tested and infected students respectively.

Home samples were analysed by an amplified *C trachomatis* test kit (TMA, Gen-Probe, San Diego, CA). Swab samples were analysed by enzyme immunoassay (Microtrak II, Behring Diagnostics, Marburg, Germany) and confirmed by DNA amplification.[5]

In the home sampling group, 1254 of 2603 (48%) females responded compared with 1097 of 2884 (38%) in the control group, and of the 1733 males in the home sampling group, 590 (34%) responded compared with 316 of 1689 (19%) in the control group (table). There was no difference in knowledge of *C trachomatis* infection between the two groups: mean age (females 18.0 years (SD 1.5 years), males 18.2 years (SD 1.7 years)); having a regular intimate relationship (47% of females and 36% of males); and presence of urogenital symptoms (12% of females and 3% of males).

In the home sampling group, 867 (93.4%) eligible females were tested compared with 63 (7.6%) in the control group ($\chi^2 = 1298$, $P < 0.001$). The figures for detected infections were 43 (4.6%) and 5 (0.6%) respectively ($\chi^2 = 26.9$, $P < 0.001$). In the home sampling group, 430 (97.3%) eligible males were tested compared with 4 (1.6%) in the control group ($\chi^2 = 620$, $P < 0.001$). The figures for detected infections were 11 (2.5%) and 1 (0.4%) respectively ($\chi^2 = 4.15$, $P = 0.042$). Statistical significance was also achieved when all students were considered the target population. The slip was returned for 95% of the infected students.

The prevalence of infection was highest in the control group, implying that students in this group were more concerned about the possibility of infection. This