**Q1.**The ‘placebo effect’ describes the improvement in patients’ symptoms due to psychological effects. Scientists investigated the placebo effect in patients with asthma. They divided a large number of asthma patients into three groups, **1**, **2** and **3**.

•        Group 1 inhaled a spray containing albuterol every day. Albuterol is a drug used to treat asthma.

•        Group 2 inhaled a placebo spray every day. This was identical to the spray given to
group 1 but it did not contain albuterol.

•        Group 3 did not receive any spray treatment.

(a)     Describe one way the scientists could have allocated the patients to each group.

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**(2)**

The scientists measured the forced expiratory volume (FEV1 ) of each patient at regular intervals. The forced expiratory volume (FEV1 ) is the volume of air forced out of the lungs in the first second when breathing out. The scientists recorded each patient’s FEV1  before treatment started and after 60 days of treatment. They then calculated the mean increase in FEV1  for each group. Their results are shown in the graph. The bars show the standard deviation.

 

Patient group

(b)     What do the standard deviation bars suggest about the difference in the mean increase in FEV1  between Group **1** and the other groups? Explain your answer.

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**(2)**

(c)     What do the data suggest about the ‘placebo effect’ in this investigation? Explain your answer.

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**(2)**

(d)     On each occasion that a patient’s FEV1  was measured, a doctor repeated the measurement several times. Explain why.

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**(2)**

(e)     All the patients continued with their normal treatment for asthma. The normal treatment was the same for all patients and its effects were short-lived. The patients were told to stop this treatment 24 hours before FEV1  measurements were taken.

(i)      Suggest why all the patients were allowed to continue with their normal asthma treatment in this investigation.

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**(1)**

(ii)     Suggest why the patients were told to stop their normal asthma treatment 24 hours before their FEV1  measurements were taken.

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**(2)**

(f)     After 60 days, the patients in each group were asked to give themselves an *Improvement* Score from 0-10 to show how much they felt their symptoms had improved. This was done before their FEV1  was measured. The scientists calculated the mean *Improvement* Score for each group.

(i)      The scientists concluded that the data obtained for the Improvement Scores were less reliable than the data obtained measuring FEV1 . Suggest why they concluded this.

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**(2)**

(ii)     Group 3 reported the lowest mean *Improvement* Score. Suggest **one** explanation for this.

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**(2)**

**(Total 15 marks)**

 **M1.**(a)     1.      Random;

*Random number generator = 2 marks*

2.      Method e.g. number generator / number out of a hat;

*Same age = 2 marks*

***OR***

3.      Matched / all the same;

4.      For e.g. age / sex;

**2 max**

(b)     1.      (Differences) are real / significant / not due to chance;

*It = the difference*

2.      (As) bars / SDs do not overlap;

*2. Accept: ‘standard errors do not overlap’ as told ‘standard deviation’ in the question stem*

**2**

(c)     1.      No / slight (placebo) effect;

2.      Group **2** and **3** results are similar / the same / SDs / bars overlap;

*2. Accept: other descriptions of Groups* ***2*** *and* ***3***

*2. Accept: that Groups* ***2*** *and* ***3*** *are not significantly different*

**2**

(d)     1.      (Allows) anomalies to be identified / ignored / effect of anomalies to be reduced / effect of variation in data to be minimised / concordant results;

*Accept: ‘outliers’ instead of anomalies*

*1. Reject: idea of not recording anomalies / preventing anomalies from occurring*

*1. Accept: ‘cancels out anomalies’ as bottom line response*

2.      (Makes) average / mean (more) reliable;

*2.* ***Q*** *Neutral: makes the average / mean more accurate*

*2. Ignore: ‘more reliable’ alone*

**2**

(e)     (i)      1.      Unethical / unfair not to treat patients;

2.      Dangerous / could cause an asthma attack;

**1 max**

(ii)     1.      Ensures normal treatment does not affect results / improvements are only due to the spray;

2.      (As) normal treatment is short-lived / effective for less than 24 hours / (24h) is long enough for normal treatment to wear off;

**2**

(f)     (i)      1.      (Improvement scores) are qualitative / subjective / rely on own judgement / different patients may assess symptoms differently;

*Accept: converse arguments for measuring FEV1 e.g. quantitative / objective patients cannot lie*

2.      Some patients may lie / exaggerate / want to please doctors;

*1. Neutral: empirical evidence*

**2**

(ii)     1.      Not blind / patients knew they were not receiving treatment / patients did not receive treatment;

2.      (So) more likely to underestimate / give lower scores / did not expect to improve / less improvement;

**2**

**[15]**

**E1.**(a)     60% of students scored full marks and the first route on the mark scheme was the most popular. Students scoring one mark typically mentioned ‘random’. However, some responses conveyed a failure to read the question stem carefully enough. Consequently, they answered a different question from the one asked and produced answers such as ‘reduces bias’, ‘use a double blind trial’, ‘ensure there is the same number of patients in each group’ and ‘do not tell patients which treatment they are receiving’.

(b)     It was disappointing that 60% of students were unfamiliar with the use of standard deviation and scored zero. Only a quarter of students stated that the bars did not overlap and related this to the difference in results between Group **1** and the other groups as being significant, or not due to chance. Weaker responses that did make reference to the standard deviation bars usually went no further than to state that the bar for Group **1** was larger than that of the other groups.

(c)     Three-quarters of students were aware that there was no evidence of a placebo effect, or that this effect was slight. However, the ability to link this to data shown in the graph proved to be a good discriminator.

(d)     Two-thirds of students gained one mark for the idea that anomalies could be identified. However, some thought that repeats prevented anomalies from occurring or being recorded. It was only the best responses that referred to allowing a more reliable mean to be calculated. Taking additional readings does not necessarily allow results to be closer to the true value. Hence, references to ‘a more accurate mean’ were not credited. Weaker responses often referred to ‘the results’ being more reliable or more accurate, without further qualification.

(e)     (i)      Just over half of students gained this mark. Students who failed to score typically repeated information given in the question stem. The most typical response seen was ‘so that the normal treatment was the same for all patients’.

(ii)     Almost all students scored at least one mark. This was usually for appreciating that the normal treatment would not affect the results. Weaker responses usually relied on vague, stock *How Science Works* phrases, e.g. ‘so a comparison can be made’, ‘it would give less reliable results’ and ‘to make it a fair test’. There was also evidence that a minority of students failed to read the question carefully enough. Their responses referred to albuterol as, the normal treatment or FEV as the experimental drug.

(f)     (i)      80% of students scored at least one mark. This was usually for stating that improvement scores are subjective or qualitative. Only 10% of students went further and suggested that some patients might lie, exaggerate or want to please doctors. Again, weaker responses typically repeated information given in the question stem, e.g. ‘the improvement score is how much the patients felt their symptoms had improved so it less reliable’.

(ii)     Almost all students scored at least one mark. This was usually for the idea that patients knew they were not receiving any treatment. However, two-thirds of students were able to complete the story by linking this to patients being more likely to give lower improvement scores.