CAP 1

(16 marks)

Please read the following abstract, table and figure and answer the questions based on this information and your other knowledge.

“Exposure-based cognitive–behavioural therapy via the internet and as bibliotherapy for somatic symptom disorder and illness anxiety disorder: randomised controlled trial

Erik Hedman, Erland Axelsson, Erik Andersson, Mats Lekander and Brjánn Ljótsson

Background:
In DSM-5 two new diagnoses, somatic symptom disorder (SSD) and illness anxiety disorder (IAD), have replaced DSM-IV hypochondriasis. There are no previous treatment studies for these disorders. Cognitive–behavioural therapy (CBT) delivered as therapist-guided or unguided internet treatment or as unguided bibliotherapy could be used to increase treatment accessibility.

Aims:
To investigate the effect of CBT delivered as guided internet treatment (ICBT), unguided internet treatment (U-ICBT) and as unguided bibliotherapy.

Method:
A randomised controlled trial (RCT) where participants (n = 132) with a diagnosis of SSD or IAD were randomised to ICBT, U-ICBT, bibliotherapy or to a control condition on a waiting list (trial registration: Clinicaltrials.gov identifier NCT01966705).

Results:
Compared with the control condition, all three treatment groups made large and significant improvements on the primary outcome Health Anxiety Inventory (between-group d at post-treatment was 0.80–1.27).

Conclusions:
ICBT, U-ICBT and bibliotherapy can be highly effective in the treatment of SSD and IAD. This is the first study showing that these new DSM-5 disorders can be effectively treated.”
Question 1

Based on the abstract and your other knowledge, which option best describes this study? (1 mark)

A. Aetiology.
B. Diagnostic categorization.
C. Intervention.
D. Observational.
E. Prognostic.
F. Qualitative.
G. Screening intervention.
H. Systematic review.
Question 2

“... Information about the study was provided via mental health and primary care personnel, newspapers with national coverage and a study web portal through which all potential participants had to apply...”

Based on the abstract, the quote above and your other knowledge, which option best describes the sampling method used? (1 mark)

A. Cluster sampling.
B. Convenience sampling.
C. Probability weighted sampling.
D. Quasi-random sampling using sequential allocation.
E. Quota sampling.
F. Simple unrestricted random sampling.
G. Snowball sampling.
H. Stratified sampling.
Question 3

Based on the abstract and your other knowledge, which option best describes the intention to treat analysis? (2 marks)

A. Excludes those who do not adhere to treatment.
B. Is another term for per protocol analysis.
C. Is biased by effects from protocol deviations, crossover and drop-outs.
D. Tends to overestimate treatment effects.
E. Increases the statistical power.
F. Is more susceptible to Type II errors than per protocol analysis.
Question 4

Based on the abstract and your other knowledge, which option best describes a Type II error? (2 marks)

A. Common in adequately powered studies.
B. Failure to reject a false null hypothesis.
C. Failure to reject a true null hypothesis.
D. Rejection of a true null hypothesis.
E. True negative.
F. True positive.
Question 5

Based on the abstract and your other knowledge, which option best describes a Type I error? (1 mark)

A. Common in adequately powered studies.
B. Failure to reject a false null hypothesis.
C. Failure to reject a true null hypothesis.
D. Rejection of a true null hypothesis.
E. True negative.
F. True positive.
Question 6

Based on the abstract, Figure 2 and your other knowledge, which option is the most appropriate statistical test for comparing the four post treatment mean Health Anxiety Inventory Scores? (1 mark)

A. ANOVA.
B. Bivariate correlation analysis.
C. Chi-square test.
D. Dependent samples t test.
E. Independent samples t test.
F. Kaplan Meier survival analysis.

Fig. 2 Change in the primary outcome measure – the Health Anxiety Inventory.

Error bars represent 95% confidence intervals. CBT, cognitive–behavioural therapy; ICBT, internet-based CBT, U-ICBT, unguided internet-based CBT.
“...At post-treatment, the proportion of participants in remission, i.e. meeting criteria for clinically significant improvement on the primary outcome measure, the HAI, was: ICBT 53%, U-ICBT 48%, bibliotherapy 44%, control condition 0%. At 6-month follow-up, the corresponding proportions were 53, 48 and 47%...”

**Question 7**

Based on the abstract, Figure 2, the quote above and your other knowledge, which option is the most appropriate statistical method for comparing the proportion of responders between the ICBT and control groups?: (1 mark)

A. ANOVA.

B. Bivariate correlation analysis.

C. Chi-square test.

D. Dependent samples t test.

E. Independent samples t test.

F. Kaplan Meyer survival analysis.
Question 8

”... The three treatments produced similar effects and there were no significant differences in improvements between them on any of the health anxiety measures. Effects were maintained at long-term follow-up and the number needed to treat to achieve one case of clinically significant improvement was about two...”

Based on the abstract, the quote above and your other knowledge, which option best describes the correct value of absolute risk reduction for clinically significant improvement? (2 marks)

A. 0.33  
B. 0.5  
C. 0.66  
D. 0.75  
E. 1.0  
F. 2.0
**Question 9**

“The three treatments produced similar effects and there were no significant differences in improvements between them on any of the health anxiety measures. Effects were maintained at long-term follow-up and the number needed to treat to achieve one case of clinically significant improvement was about two...”

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**Table 2** Means and effect sizes (Cohen’s d) on primary outcome measure

<table>
<thead>
<tr>
<th>Health Anxiety Inventory (scale range: 0–192)</th>
<th>Mean (s.d.)</th>
<th>6-month follow up</th>
<th>Within-group, pre-post treatment</th>
<th>Within-group, pre-6-month follow-up</th>
<th>Between-group, post-treatment</th>
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</thead>
<tbody>
<tr>
<td>ICBT</td>
<td>105.5 (21.4)</td>
<td>69.7 (24.8)</td>
<td>59.5 (31.3)</td>
<td>1.55 (0.87–2.22)</td>
<td>2.23 (1.31–3.14)</td>
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<td>U-CBT</td>
<td>109.1 (25.8)</td>
<td>68.3 (35.6)</td>
<td>62.9 (34.2)</td>
<td>1.31 (0.84–1.78)</td>
<td>1.52 (0.90–2.15)</td>
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<tr>
<td>Bibliotherapy</td>
<td>114.5 (21.3)</td>
<td>75.5 (35.0)</td>
<td>71.5 (31.3)</td>
<td>1.35 (0.88–1.82)</td>
<td>1.61 (1.05–2.16)</td>
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<tr>
<td>Control condition</td>
<td>108.2 (24.1)</td>
<td>100.1 (26.1)</td>
<td>--</td>
<td>0.29 (0.15–0.42)</td>
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</tr>
</tbody>
</table>


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Based on the abstract, Table 2, the quote above and your other knowledge, which option best describes the significance and generalisability of the results? (1 mark)

A. Statistically and clinically significant with good generalisability.

B. Statistically significant but clinically insignificant.

C. Statistically and clinically significant with limited generalisability.

D. Statistically insignificant but clinically significant.

E. Statistically and clinically insignificant.

F. Statistically and clinically significant with no generalisability.
Question 10

“The three treatments produced similar effects and there were no significant differences in improvements between them on any of the health anxiety measures. Effects were maintained at long-term follow-up and the number needed to treat to achieve one case of clinically significant improvement was about two...”

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Based on the abstract, Table 2, the quote above and your other knowledge, which option best describes the effect size? (1 mark)

A. Effect sizes for the active treatment conditions are large.
B. Effect sizes for the active treatment conditions are moderate.
C. Effect sizes for the active treatment conditions are small.
D. Only ICBT pre-post treatment, pre-6-month follow-up has a significant effect size.
E. Patients who had ICBT were 1.27 times as likely as those in the control condition to respond.
Question 11

Based on the abstract and your other knowledge, which option best describes the type of methodological problem addressed by randomising participants to different groups? (1 mark)

A. Attrition bias.
B. Ethical concerns.
C. Inadequate sample size.
D. Information bias.
E. Measurement bias.
F. Publication bias.
G. Recall bias.
H. Selection bias.
Question 12

Based on the abstract and your other knowledge, which option best describes the type of methodological problem addressed by an a priori power analysis? (1 mark)

A. Attrition bias.
B. Ethical concerns.
C. Inadequate sample size.
D. Information bias.
E. Measurement bias.
F. Publication bias.
G. Recall bias.
H. Selection bias.
Question 13

Based on the abstract and your other knowledge, which option best describes the type of methodological concern addressed by conducting an intention to treat analysis?  

A. Attrition bias.
B. Ethical concerns.
C. Inadequate sample size.
D. Information bias.
E. Measurement bias.
F. Publication bias.
G. Recall bias.
H. Selection bias.