



CRITICAL ANALYSIS PROBLEMS

MOCK EXAMINATION

Paper II

2014

STIMULUS

To be used as a handout while answering questions.

This Stimulus must be collected by the invigilator at the end of examination.

The various extracts, figures and tables have been linked to questions to help orient candidates re where they occur in the CAP booklet, but note that the information in any of these extracts may be used to answer any sub-questions within a CAP.

Critical Analysis Question ① (20 marks)

Please read the following extracts, tables and figures and answer the questions according to this information and your other knowledge.

Olanzapine vs. risperidone in treating aggressive behaviours in adults with intellectual disability: a single blind study

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Abstract:

Background: Aggressive behaviour represents a frequent symptom in people with intellectual disability (PWID). Despite uncertain evidence of effectiveness, the use of antipsychotics (APs) drugs to treat aggressive behaviour is very common. Antipsychotic medication of aggressivity in PWID has recently become one of the most debated issues in mental health and the need of further research is persistently stressed by most researchers.

Aim: The present study was firstly aimed at evaluating the effectiveness (efficacy on target behaviour, safety and persistence on treatment) of new generation APs, in particular, olanzapine and risperidone in treating aggressive behaviour in PWID for who previous medication with first generation APs (FGAs) were not effective.

Methods: 62 subjects with intellectual disability underwent to a 2-arm, parallel group pragmatic trial of olanzapine and risperidone with balanced randomisation and blind assessment of outcome at 4, 8, 12, 16, 20 and 24 weeks after a switch (cross-tapering) from a 24-week treatment with FGAs. Aggressive behaviours were assessed by Overt Aggression Scale (OAS) and clinical outcome by Clinical Global Impression Scale. Side effects were assessed with Dosage Record and Treatment Emergent Symptoms Scale, other symptom-specific scales, laboratory and instrumental tests.

Results: Both risperidone and olanzapine resulted to be more effective than FGAs in reducing aggressive behaviour. Repeated-measures analysis of covariance revealed that treatment groups differed for cumulative number of aggressive episodes during the FGAs treatment, which was higher for olanzapine.

Conclusion: Our findings seem to confirm that olanzapine and risperidone can be effective in reducing aggressive behaviour in PWID. Both compounds resulted to be well tolerated, with side effects similar to those encountered in other patient populations.

Keywords aggressive behaviour, antipsychotics, atypical, intellectual disability, olanzapine, risperidone

QUESTIONS 1.11 to 1.13

Answer the following questions having regard to the extract and table below, the abstract, and your other knowledge. (FGA = First Generation Antipsychotic)

Sample:

Participants in the study were consecutive patients attending a specialist mental health service for PWID (Istituto Ospedaliero 'Fondazione Sospiro' di Sospiro – Cremona) covering an area of 154 677 inhabitants of the North Italy. A total of 62 adults (mean age of 48 ± 12.45 years), of which 17 were female (27.4%) and 45 male (72.6%), were recruited to the study between November 2005 and December 2006 from a catchment area of approximately 800 users. Subjects in the study were in residential care, with Diagnostic and Statistic Manual-IV Edition Text Revision (DSM-IV TR) (American Psychiatric Association 2000) diagnosis of Severe Mental Retardation (Wechsler-Bellevue for IQ; Wechsler 1944) and aggressive behaviours, which had not changed with previous FGAs treatments. All of them had a Clinical Global Impression-Severity (CGI-S) score of 5 (markedly ill).

At the beginning of the study, all patients were receiving a FGAs and after a period of 24 weeks, 31 (50%) were randomised to olanzapine and 31 (50%) to risperidone.

Baseline characteristics (age, gender, level of ID and number of years of previous therapy) were collected at the beginning of the study (see Table 1).

Before the observational period on FGAs, all subjects were not receiving any antipsychotic or mood stabiliser.

Table 1 Baseline characteristics of the sample

Characteristics	
Age (years)	
Mean	48
SD	12.45
Gender, <i>n</i> (%)	
Male	45 (72.6)
Female	17 (27.4)
Level of intellectual disability, <i>n</i> (%)	
Mild	0 (0)
Moderate	0 (0)
Severe	62 (100)
Previous years of therapy, <i>n</i> (%)	
<5	5 (8)
5–20	20 (32.3)
>20	37 (59.7)

Statistical Analysis:

Data were analysed with spss version 12.0 for Windows. Statistical tests for comparison between the two groups on their characteristics included 2-sample *t*-tests for continuous variables and chi-square test for categorical variables. Multivariate analyses of continuous outcomes were by regression, with adjustment for baseline value of the response variable. Repeated-measures analysis of covariance (ANOVA) was used to examine the OAS scores ante and post switch to the two treatment groups (olanzapine and risperidone).

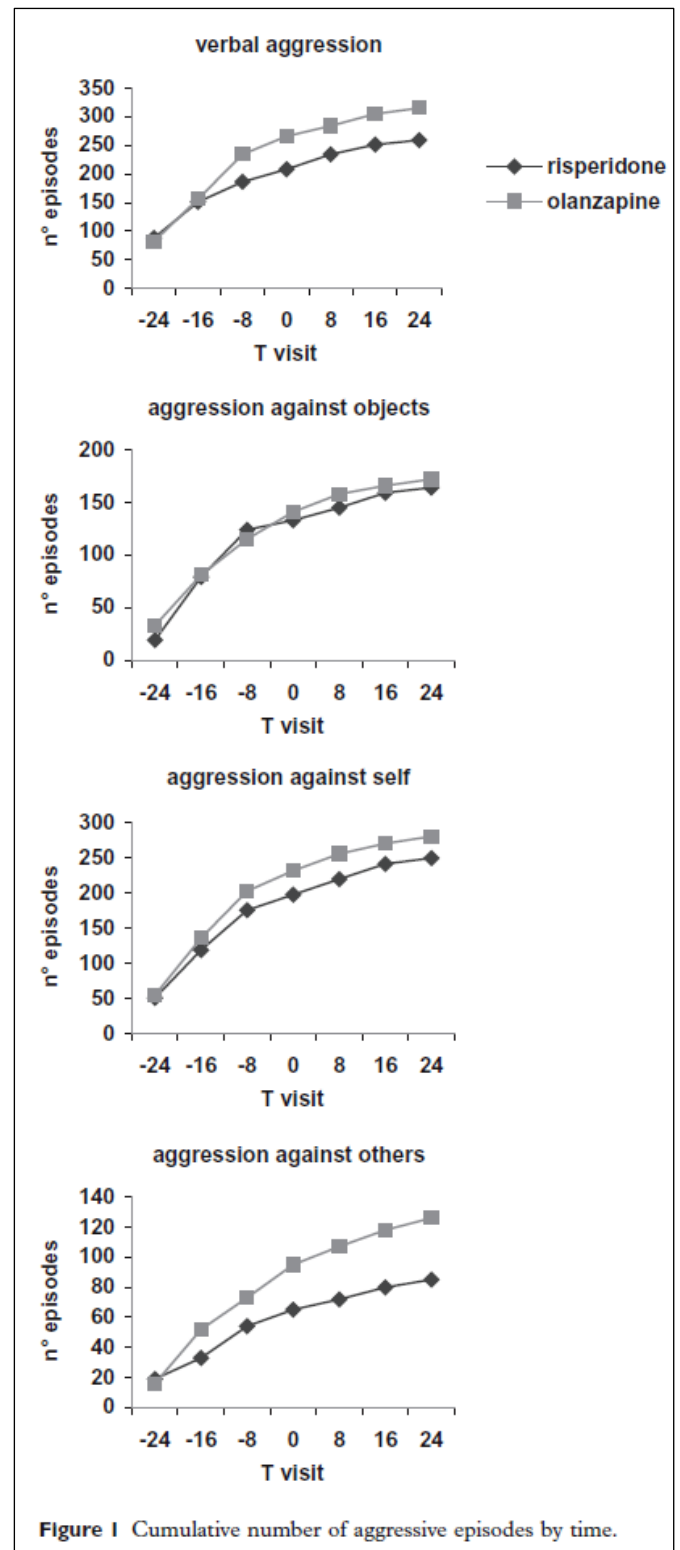
QUESTIONS 1.31 – 1.34

Extract from Results – Both olanzapine and risperidone had shown statistically significant reduction on episodes of physical aggression ($p < 0.0001$).

Table 2 Clinical global impression (CGI) improvement by treatment

CGI improvement	Olanzapine <i>n</i> (%)	Risperidone <i>n</i> (%)
Very much improved	9 (29)	19 (61.3)
Much improved	12 (38.8)	10 (32.2)
Minimally improved	10 (32.2)	2 (6.5)
Total	31 (100)	31 (100)

QUESTIONS 1.41 – 1.43



Critical Analysis Question **2** (20 marks)

Please read the following extracts, tables and figures and answer the questions according to this information and your other knowledge.

Internet-based cognitive–behavioural therapy for severe health anxiety: randomised controlled trial

Erik Hedman, Gerhard Andersson, Erik Andersson, Brjánn Ljótsson, Christian Rück, Gordon J. G. Asmundson and Nils Lindefors

Background
Hypochondriasis, characterised by severe health anxiety, is a common condition associated with functional disability. Cognitive–behavioural therapy (CBT) is an effective but not widely disseminated treatment for hypochondriasis. Internet-based CBT, including guidance in the form of minimal therapist contact via email, could be a more accessible treatment, but no study has investigated internet-based CBT for hypochondriasis.

Aims
To investigate the efficacy of internet-based CBT for hypochondriasis.

Method
A randomised controlled superiority trial with masked assessment comparing internet-based CBT ($n=40$) over 12 weeks with an attention control condition ($n=41$) for people

with hypochondriasis. The primary outcome measure was the Health Anxiety Inventory. This trial is registered with ClinicalTrials.gov (NCT00828152).

Results
Participants receiving internet-based CBT made large and superior improvements compared with the control group on measures of health anxiety (between-group Cohen's d range 1.52–1.62).

Conclusions
Internet-based CBT is an efficacious treatment for hypochondriasis that has the potential to increase accessibility and availability of CBT for hypochondriasis.

Declaration of interest
None.

Having regard to the abstract above and your other knowledge:

QUESTIONS 2.11 – 2.12

Having regard to the abstract, the extract below regarding the inclusion criteria, and your other knowledge:

QUESTION 2.21

To be eligible for inclusion, potential participants had to meet the following criteria:

- (a) agree to not undergo any other psychological treatment for the duration of the study;
- (b) have no history of CBT in the past 4 years;
- (c) have no serious somatic disease as assessed by a physician based on a review of medical records and the anamnesis from the diagnostic assessment interview;
- (d) constant dosage 2 months prior to treatment if on prescribed medication for anxiety or depression and agree to keep dosage constant throughout the study;
- (e) fulfil the DSM–IV criteria of hypochondriasis as assessed using the Health Anxiety Interview;
- (f) other comorbid disorders according to the Mini International Neuropsychiatric Interview (MINI) were allowed but hypochondriasis had to be the primary concern;
- (g) not currently fulfilling the diagnostic criteria for substance misuse according to the MINI;
- (h) have no history of psychosis or bipolar disorder;
- (i) not score 420 on the Montgomery–Åsberg Depression Rating Scale–Self-Report (MADRS–S) if criteria for major depression were met;
- (j) have a score of less than 4 of 6 on the suicide ideation item of MADRS–S; and
- (k) not meet criteria for any personality disorders within cluster A or B according to the DSM–IV.

QUESTION 2.31

Assessments, including diagnostic interviews performed by a clinical psychologist, were conducted before treatment, after treatment and at 6-month follow up...

The clinical psychologists performing the assessments were masked to treatment status ...

...all participants were instructed not to mention assessment.

Following the study the psychologists guessed allocation status for each participant.

Having regard to the information below, the abstract and your other knowledge:

QUESTION 2.41

Control condition

The control condition consisted of an online discussion forum where participants could send messages anonymously to each other over a period of 12 weeks. Online discussion forums have been shown to be effective in reducing depressive symptoms and anxiety in people with depression and breast cancer.

QUESTIONS 2.51 – 2.53

The statistical analysis mentions: "power calculations showed that there was a chance slightly lower than 80% to detect a difference, given an effect size of 0.6 and an alpha level of 0.05."

Having regard to the following extract from the Interventions, Fig 2 and Table 2 below, the abstract and your other knowledge:

QUESTIONS 2.61 – 2.71

A central feature of the treatment was a self-help text of 118 pages, divided into 12 modules. Participants gradually gained access to the modules through an internet-based treatment platform. Each module was devoted to a specific theme and included homework exercises. The modules reflected the content of conventional CBT for hypochondriasis. The treatment protocol was developed by our research group and it has been validated in a trial investigating the effects of group CBT for hypochondriasis. A detailed description of each module can be found in Fig. 2.

The duration of the internet-based CBT was 12 weeks and throughout this period the participant had access to a therapist via a secure online contact system. The role of the therapist was mainly to provide feedback regarding all homework and to grant access to the succeeding treatment modules; however, the participant could contact the therapist at any time and expect a reply within 24 h. In addition, therapists encouraged inactive participants to continue the treatment work. The participant and therapist had no face-to-face or telephone contact during the treatment. On average, therapists spent 9 min (s.d.=5.6) weekly per participant. During the treatment phase, participants also had access to an online discussion forum that enabled anonymous contact with other participants receiving internet-based CBT.

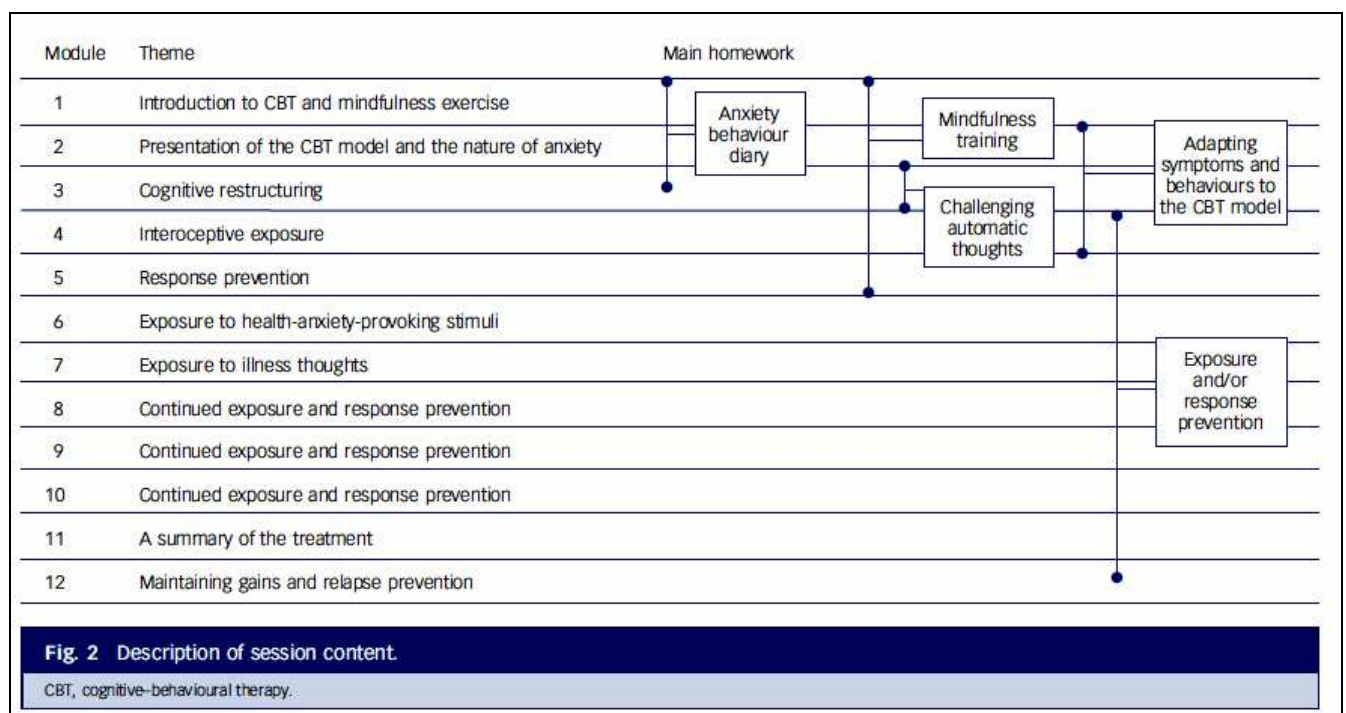
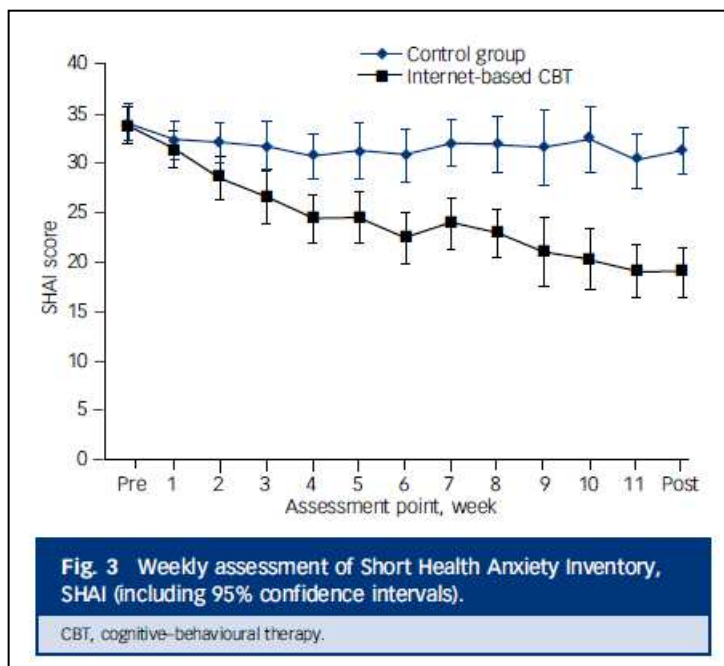


Table 2: Number of participants in the internet based CBT group completing each module

Number of Completed Modules												
	≥1	≥2	≥3	≥4	≥5	≥6	≥7	≥8	≥9	≥10	≥11	≥12
Internet Based CBT, n (%)	40 (100)	39 (97.5)	39 (97.5)	37 (92.5)	35 (87.5)	33 (82.5)	29 (72.5)	26 (65.0)	23 (57.5)	22 (55)	21 (52.5)	14 (35.0)

Measure (scale range)	Mean (s.d.)			Effect size, <i>d</i> (95% CI)		
	Pre-treatment	Post-treatment	6-month follow-up	Between-group, post-treatment	Within-group, pre-treatment-post-treatment	Within-group, pre-treatment-6-month follow-up
Health Anxiety Inventory (0 to 192) Internet-based cognitive-behavioural therapy group Control group	107.0 (22.0) 106.0 (16.6)	60.5 (25.7) 101.8 (25.4)	56.2 (26.4)	1.62 (1.10 to 2.10)	1.94 (1.39 to 2.45) 0.19 (–0.24 to 0.62)	2.09 (1.52 to 2.61)
Illness Attitude Scales (0 to 112) Internet-based cognitive-behavioural therapy group Control group	69.8 (11.7) 67.6 (10.9)	44.6 (16.4) 65.4 (11.8)	41.3 (16.9)	1.46 (0.95 to 1.93)	1.77 (1.24 to 2.27) 0.19 (–0.24 to 0.62)	1.96 (1.41 to 2.48)
Whiteley Index (0 to 14) Internet-based cognitive-behavioural therapy group Control group	10.7 (2.09) 10.5 (2.1)	10.3 (2.1) 6.1 (3.3)	5.3 (3.4)	1.52 (1.01 to 2.00)	1.65 (1.12 to 2.14) 0.09 (–0.34 to 0.53)	1.89 (1.35 to 2.40)
Montgomery-Åsberg Depression Rating Scale – Self-Report (0 to 54) Internet-based cognitive-behavioural therapy group Control group	12.3 (5.9) 13.7 (7.6)	5.6 (4.3) 12.3 (6.6)	6.5 (7.2)	1.21 (0.73 to 1.67)	1.32 (0.83 to 1.79) 0.20 (–0.24 to 0.63)	0.90 (0.43 to 1.35)
Beck Anxiety Inventory (0 to 63) Internet-based cognitive-behavioural therapy group Control group	21.0 (11.4) 21.3 (12.3)	10.7 (9.1) 21.9 (12.0)	9.2 (10.3)	1.05 (0.58 to 1.51)	1.00 (0.53 to 1.45) –0.05 (–0.48 to 0.39)	1.09 (0.61 to 1.55)
Anxiety Sensitivity Index (0 to 64) Internet-based cognitive-behavioural therapy group Control group	26.0 (12.1) 26.8 (11.0)	14.1 (8.0) 25.6 (10.4)	12.6 (10.4)	1.24 (0.75 to 1.70)	1.16 (0.68 to 1.63) 0.11 (–0.32 to 0.54)	1.19 (0.71 to 1.66)
Quality of Life Inventory (–6 to 6) Internet-based cognitive-behavioural therapy group Control group	1.9 (1.3) 1.4 (1.5)	2.4 (1.4) 1.3 (1.6)	2.4 (1.5)	0.74 (0.28 to 1.18)	0.37 (–0.07 to 0.81) 0.06 (–0.38 to 0.49)	0.34 (–0.10 to 0.78)
Global Assessment of Functioning (0 to 100) Internet-based cognitive-behavioural therapy group Control group	54.8 (3.1) 55.0 (4.3)	71.7 (10.0) 58.7 (7.8)	2.4 (1.5)	–1.45 (–1.93 to –0.95)	–2.29 (–2.82 to –1.70) –0.59 (–1.03 to –0.14)	–2.78 (–3.36 to –2.14)

Having regard to Figure 3 below and the following Results extract:



The ANCOVA for HAI difference at post-treatment assessment, holding pre-treatment values as covariates, revealed a significant effect between the internet-based CBT group and the control group ($F=95.90$, $d.f.=1,78$, $P50.001$). As illustrated in Fig. 3, the internet-based CBT group displayed continuous within-group improvements throughout the trial on the SHAI. Analysis using the mixed-effects model showed a significant interaction effect of group and time on the SHAI ($F=17.14$, $d.f.=12,823$, $P50.001$). *Post hoc* tests showed that participants in the internet-based CBT group had significantly lower scores than those in the control group from the third week onwards ($t=2.39-7.03$, $d.f.=1,60-79$, $P50.001$).

QUESTIONS 2.81 – 2.82