NUFFIELD DEPARTMENT OF
PRIMARY CARE
HEALTH SCIENCES

UNIVERSITY OF
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Extending the treatment options in alcohol dependence

Student EBM presentations

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Drug recommended to help cut drink dependence

The pill reduces the urge to drink alcohol

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The question

Scenario:

Mrs. Jones, a 35 year old lady, visited her GP previously due to her dependence on alcohol but refused psychiatric support as treatment. She has recently heard that NICE has approved a new drug, nalmefene, to help reduce alcohol consumption and asks her GP whether it might be appropriate for her.

Clinical question:

Does the drug nalmefene help to reduce alcohol consumption in previously untreated adults with alcohol dependance?

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Clinical question:
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P	Patients who are dependent on alcohol, who have not been treated previously
I	The drug nalmefene
C	A placebo drug and/or the best current psychiatric support
O	Patients have a reduced alcohol consumption and reduced dependence

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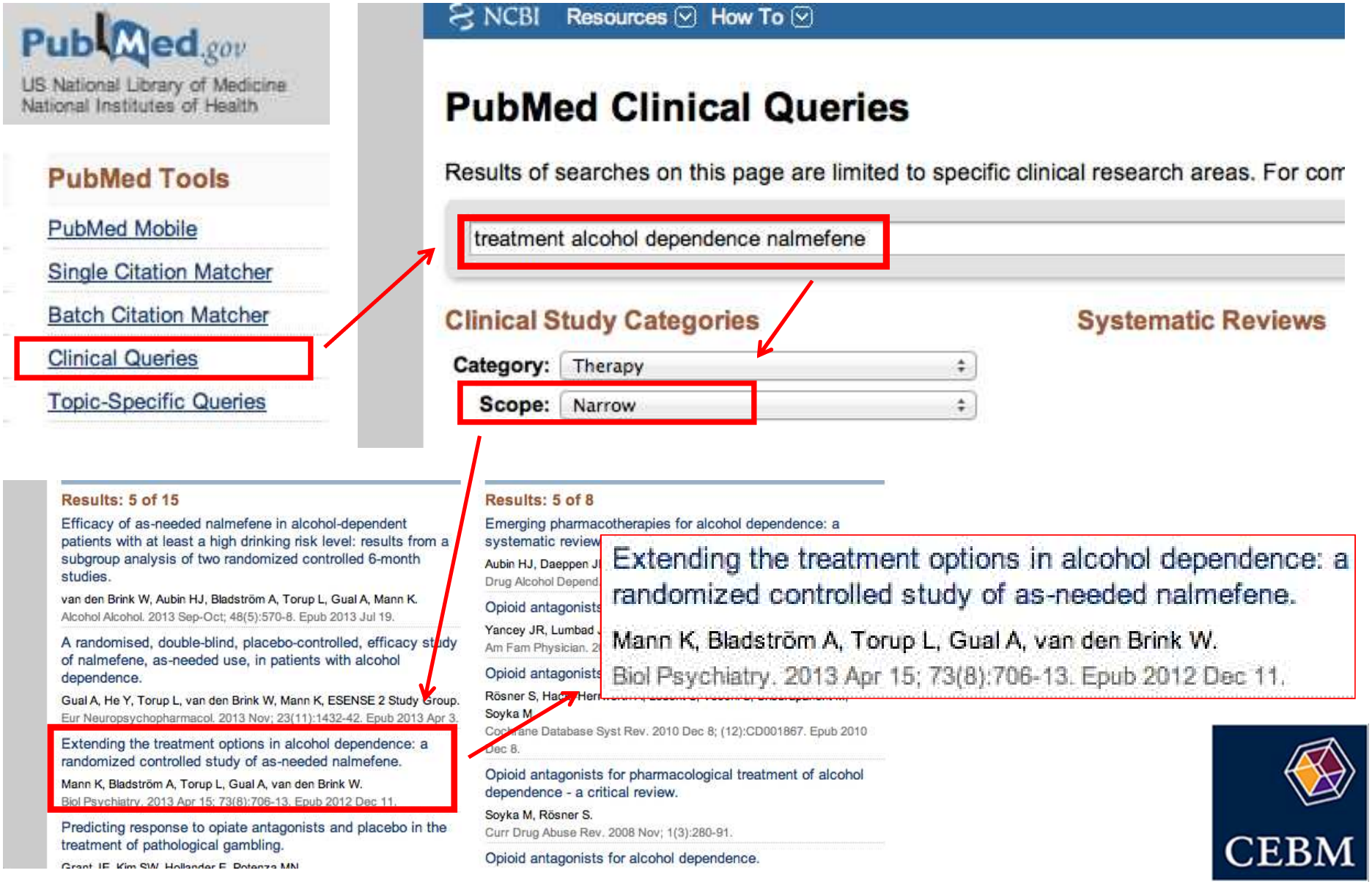
The search and search results



The study

- Compared 18mg as-needed nalfemene/placebo over a 24 week period in conjunction with BRENDA
- Primary outcome was total number of heavy drinking days per month in addition the amount of alcohol consumed
- The paper concluded nalfemene has a clinically significant benefit

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The study appraisal

Recruitment	Were the subjects representative of the target population?
Allocation	How was the randomisation carried out? Was allocation concealed?
Maintenance	Were the groups equal at the start? And maintained through equal management and f/u?
Blinding (measurement)	Were the outcomes measured with blinded assessors/participants?
Objective outcomes (measurement)	Were there differences in how outcomes were determined?

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The Results (interpretation of findings)

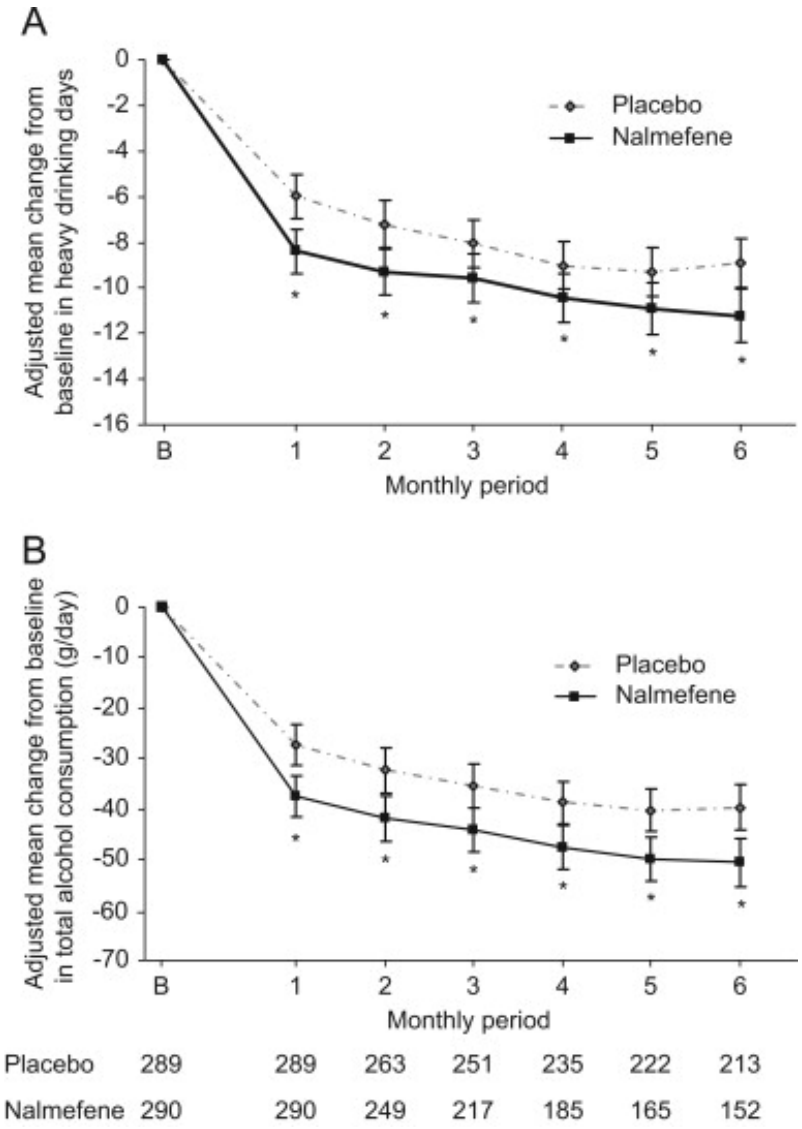

Table 3. Adverse Events in All-Patients-Treated Set

	Placebo ($n = 296$)	Nalmefene ($n = 302$)
Treatment-Emergent Adverse Events[a]	198 (66.9)	246 (81.5)
Treatment-Emergent Adverse Events (≥5%)		
Dizziness	23 (7.8)	83 (27.5)
Nausea	18 (6.1)	83 (27.5)
Fatigue	25 (8.4)	53 (17.5)
Headache	27 (9.1)	36 (11.9)
Nasopharyngitis	37 (12.5)	34 (11.3)
Sleep disorder	1 (.3)	32 (10.6)
Insomnia	10 (3.4)	30 (9.9)
Vomiting	8 (2.7)	24 (7.9)
Hyperhidrosis	5 (1.7)	16 (5.3)
Treatment-Emergent Adverse Events Leading to Dropout[a]	22 (7.4)	69 (22.8)
Treatment-Emergent Adverse Events Leading to Dropout (≥2%)		
Dizziness	0 (.0)	16 (5.3)
Nausea	0 (.0)	16 (5.3)
Fatigue	0 (.0)	10 (3.3)
Headache	0 (.0)	9 (3.0)
Serious Adverse Events[b]	20 (6.7)[c]	18 (5.9)

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The Implications

- Quality of analysis
- Involvement of the sponsor
- High risk of adverse events
- Implications for the patient?

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