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Alcohol brief intervention for people with chronic viral hepatitis: A randomised controlled trial.

Dr Carol Reid, Lecturer, School of Nursing,
Queensland University of Technology.

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Goals and Objectives

Goal To determine the effectiveness of assessment, brief intervention (BI) and routine care compared to routine care only (no formalised intervention) for patients with chronic viral hepatitis.

Objectives To identify if assessing for alcohol use using the AUDIT C, TLFB_A and BI using the 5As model along with routine care will:

1. change levels of alcohol consumption in people with chronic viral hepatitis as measured by the TLFB_A.
2. effect quality of life in people with chronic viral hepatitis as measured by the World Health Organisation Quality of Life–Bref questionnaire (WHOQOL-BREF).

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Discussion will include:

1. Background
2. Aims
3. Research Design
4. Inclusion Criteria
5. Exclusion Criteria
6. Data Collection
7. Sample size and Measurements
8. Interventions
9. Data Analysis
10. Results
11. Strengths, Limitations, Implications and Conclusions

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Background

- Australia: prevalence of high risk drinking or dependence is estimated at 5% of the population with 15% of these considered at risk of harm.

- Excessive alcohol use is associated with increased levels of several co morbidities including cancer.

- A significant synergy exists between heavy alcohol consumption and hepatitis virus infection (hepatitis B and C), which may suggest a common pathway for hepatocarcinogenesis.

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Background

- Hepatitis C (HCV) is a common cause of cirrhosis with alcohol consumption further leading to an accelerated development of fibrosis[4].

- Patients with chronic hepatitis virus infections should consider abstaining from consuming alcohol.

- Assessment and brief interventions for behaviour change in primary care being advocated for reducing harmful alcohol consumption.

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Aims of Study

This study aimed to determine:

- the effectiveness of assessment, brief intervention (BI) and routine care compared to routine care only (no formalised intervention) for patients with chronic hepatitis B and C and who attended the Hepatology clinics at the RBWH.
- the validity of current practices
- its applicability to this population.

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Research Design

- A Randomised Controlled Trial was conducted
- Computer generated random numbers
- Clinician blinded to randomisation
- Participants blinded to intervention

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Inclusion Criteria

- People who consumed alcohol;
- Were over the age of 18 years;
- Spoke and read English; and who attended the Hepatology clinics at the hospital for the management of chronic viral hepatitis (B and C).

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Exclusion Criteria

- People who were at the time of the study, undergoing interferon based treatment were excluded from the study as symptoms from treatment could have a confounding effect upon the health outcomes being measured in the project.

- People who were assessed as being acutely mentally unwell or did not speak English were also excluded from the study as the instruments used in this study have not yet been validated in these populations.

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Data Collection

Date 1
Baseline

Date 2
Week 4

Date 3
Week 8

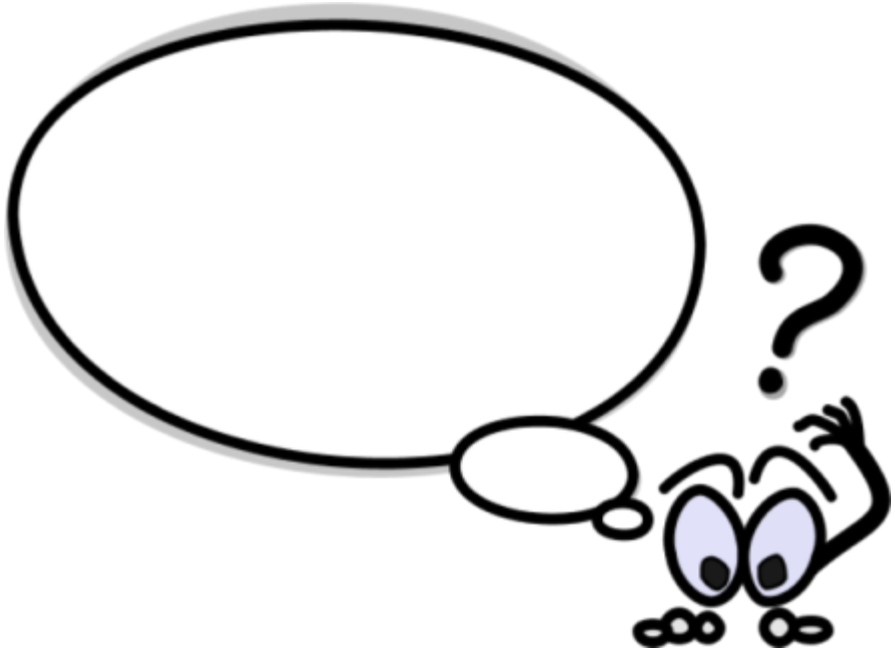
Data collected included:

(1) Alcohol consumption scores as measured by the TLFB_A;

(2) Risky Drinking (AUDIT-C)

(3) Quality of life as measured by the WHOQOL-Bref.

Sample Size & Measurements



- The sample was 66 people
- AUDIT C _ Risky drinking
- TLFB_A _ number of drinks
- World Health Organisation Quality of Life – Brief questionnaire (WHOQOL-BREF) [8].

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Interventions

Intervention Group: (Alcohol use assessment and BI)

- were assessed for alcohol consumption using the Audit-C and received the BI using the 5As model from the NP. The 10 minute intervention was conducted as a part of the routine 30 minute appointment.
- The 5As model consisted of **Assessing** people for their alcohol use, readiness to quit/reduce, and level of alcohol dependence; **Advising** how they may stop drinking and the provision of evidence based written information; **Agreeing** on a realistic set of goals with the patient; **Assisting** with a plan to stop drinking and **Arranging** follow up with a specialist Alcohol and Drug service.

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Interventions

Control Group: Routine Care: **(no formalised alcohol assessment or BI)**

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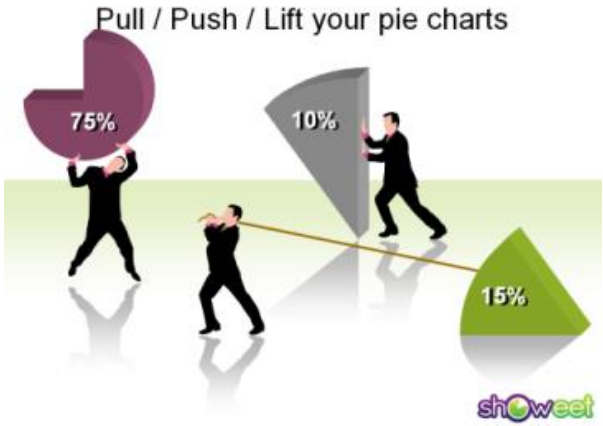
Data Analysis

- Data were analysed using SPSS



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Results

- Demographics: Age (only) differed between the intervention group and the control group

- QOL remained relatively stable over time with no significant change between groups (This was a good thing)

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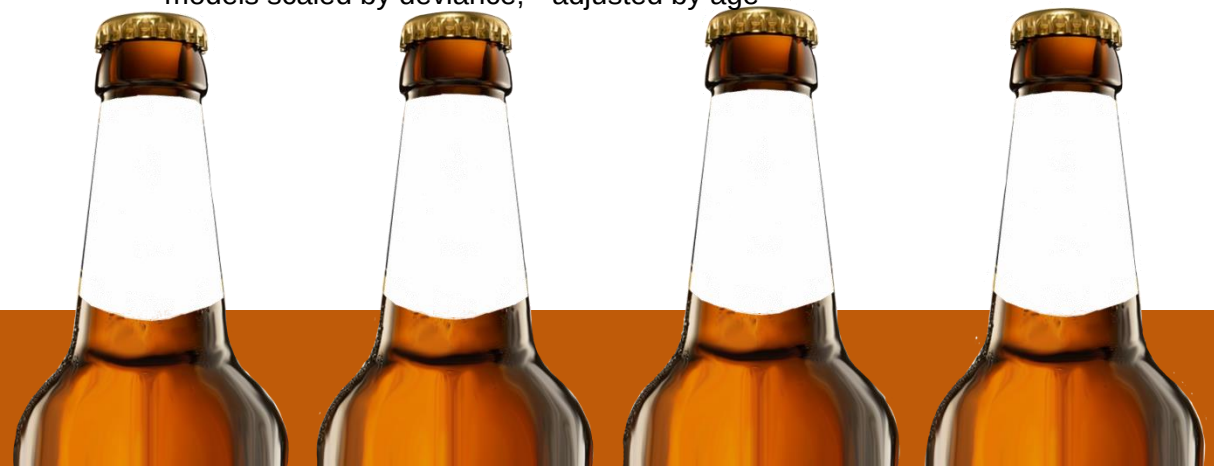
Results

Variable	Group	Baseline		4 weeks		8 weeks p-value	
		OR (95% CI)	p-value	OR (95% CI)	p-value	OR(95% CI)	p-value
Number of days where no alcohol was consumed	Control	1.00	0.848	1.00	0.420	1.00	0.697
	Intervention	1.1 (0.6, 1.9)		1.2 (0.8, 1.9)		1.2 (0.5, 2.5)	
Number of days where alcohol was consumed at high risk (5+)	Control	1.00	0.779	1.00	0.670	1.00	0.637
	Intervention	1.1 (0.5, 2.3)		0.8 (0.3, 2.2)		0.8 (0.2, 2.4)	

[1] models scaled by deviance; [2] adjusted by age



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Results

Variable	Group	baseline	6 weeks	12 weeks
		mean (95% CI)	mean (95% CI)	mean (95% CI)
Audit C	control	6.6 (5.6, 7.6)	6.0 (4.7, 7.4)	5.7 (4.5, 7.0)
	intervention	7.2 (6.2, 8.2)	5.4 (4.0, 6.8)	5.1 (3.8, 6.3)
TLFB_A[2]	control	47.3 (31.3, 71.1)	31.6 (15.9, 62.1)	22.8 (9.8, 51.6)
	intervention	55.4 (37.2, 82.5)	13.4 (6.6, 26.3)	8.6 (3.4, 20.1)

NB: [1]Models adjusted for age, [2] TLFB_A has been logarithmically transformed and back transformed means and 95% confidence intervals are reported.

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Results

- The results showed a reduction in Audit C scores over time (p=0.001). Mean Audit C scores were significantly lower at 4 weeks and 8 weeks compared to baseline, (This means significantly less risky drinking).
- There was no significant difference found between the two groups (p=0.776). There was also no significant interaction found between time and group (p=0.179), however, the intervention group tended to have a slightly higher reduction over time.
- The results of TLFB_A were also found to significantly reduce over time (p<0.001) with mean TLFB_A at 4 weeks 20.7 (p<0.001) and 8 weeks 14.1 (p<0.001) significantly lower than baseline 51.2. The intervention group generally reported a lower mean TLFB_A compared to the control group .
- A clear trend emerged with the intervention group having a much sharper sustained drop in TLFB_A over time

NB this result was found to be clinically significant, however, not found to be statistically significant (p=0.073).....but heading in the right direction

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Strengths

- The study design was a randomised controlled trial.
- The participants in the study were unaware as to which treatment group they were assigned and were not aware as to when the intervention would be given. (limiting **study bias**)
- The participants and the NP providing the intervention were blinded to the randomisation process thus limiting the potential for **selection bias** in this study.
- Additionally the control group did not receive any intervention from the NP at their appointments other than being asked to complete the questionnaire prior to randomisation. This limited **intervention contamination**.
- It is recognised however, that this process of assessment using the questionnaire for the control group may have provided an intervention.
- It is the intention now for the NP to provide the control group with the BI intervention now the study has been completed.

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Limitations

- Firstly the required sample size was not reached. Caution should therefore be taken in the interpretation of the results. There were a number of reasons for this smaller sample size, including patients being lost to follow up or they did not attend their appointments.
- Recruitment over a longer period of time would have provided sufficient participants for this study.
- It was the intention to collect objective data from blood pathology tests results such as ALT, AST and GGT opportunistically from the medical records. Unfortunately insufficient data was available to measure these outcomes by the end of the study.
- Future studies would need to ensure more rigorous methods were included for this data to be collected accurately. Furthermore the duration for this study was 8 weeks. It would be recommended to conduct future studies over a longer period of time to identify the sustainability of the intervention.

Implications for Practice

This study investigated interventions that increased the nurse practitioner's participation in the primary care setting.

- Anecdotal information from the participants and the nurse practitioner suggested the brief intervention using motivational interviewing and the 5As model was easy to implement and its' use was accepted by both staff and participants.
- The intervention also has shown the potential to reduce lifestyle risk factors in people with chronic viral hepatitis such as alcohol consumption, which are known to increase the risk of progressive liver disease and mortality.

Implications for Research

- Further robust RCTs using this intervention and outcome measures, with larger sample sizes and this patient group over longer periods of time are needed to confirm the benefits of the interventions found in this study in relation to patient outcomes.
- Larger studies should also use relevant objective measures such as regular blood pathology tests ALT , AST and GGT to support the patient reported outcome measures used.
- This brief intervention should be further developed and tested as part of a clinical pathway for people with chronic viral hepatitis attending primary health care settings.

Conclusion

- Assessing for alcohol use using the AUDIT C and TLFB_A, and providing a brief intervention using motivational interviewing and the 5As model by the Nurse Practitioner, Hepatology compared to routine care was an acceptable and useful intervention to reduce alcohol consumption in people with chronic viral hepatitis in this primary care setting.

- High levels of quality of life were perceived by the participants in both groups and no change was found to occur over time.

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QUESTIONS

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