The effect of acupuncture on people with hepatitis C virus: A randomised controlled pilot study.

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Contents

		Page Number
Acknowledgements		i
List of conference presentations and posters arising from research		iv
Contents		v
Figures		ix
Tables		xi
Abbreviations - Acronyms		xiii
Abstract		xv
Chapter 1	Introduction	1
1.1	Rationale for the study	1
1.2	Aim of the study	1
1.3	Format of the thesis	2
Chapter 2	Background	5
2.1	What is HCV?	5
2.1.1	Pathology testing	5
2.1.2	HCV prognosis and progression	7
2.1.3	HCV genotypes	9
2.1.4	Signs and symptoms of HCV	10
2.1.5	Risk factors/transmission	11
2.1.6	Global snapshot	11
2.1.7	Australian snapshot	11
2.1.8	Epidemiology	12
2.2	Current medical treatment	12
2.3	Traditional Chinese Medicine	12
Chapter 3	Literature review	15
3.1	Types of studies	15
3.2	Exclusion of studies	16

Page Number

3.3 Acupuncture 18
3.4 Chinese Herbal Medicine (CHM) 19
3.5 Summary of study findings 22
3.6 Monitoring and outcome measures 23
3.6.1 Health related Quality of Life assessment (QoL) measures 23

Chapter 4 Methods 26
4.1 Recruitment 26
4.1.1 Recruitment strategies 26
4.1.2 Enrolment 26
4.1.3 Inclusion criteria 29
4.1.4 Exclusion factors 29
4.2 Randomisation 29
4.3 Design 30
4.4 Interventions 30
4.4.1 Verum acupuncture 31
4.4.2 The control intervention 31
4.5 Outcome measures 34
4.5.1 Primary - ALT 34
4.5.2 Secondary outcome measure
– HCV PCR quantitative (viral load) test 35
4.5.3 Secondary outcome measure
- Quality of Life questionnaire 35
4.5.4 Acupuncture Treatment Credibility Questionnaire 37
4.5.5 Acupuncture Needling Sensation Questionnaire 38
4.5.6 Manualisation of HCV disease using TCM patterns 39
4.5.7 TCM Pattern reassessment 45
4.6 Ethics approval 46
4.7 Statistical analysis 46

			Page Number
Chapter 5	Results		47
5.1	Participants		47
5.2	Baseline characteristics		47
5.3	Outcome measures		49
	5.3.1	ALT levels	49
	5.3.2	HCV PCR quantitative (viral load) pathology tests	52
	5.3.3	Quality of Life (QoL) questionnaire	54
	5.3.4	Acupuncture Treatment Credibility Questionnaire	58
	5.3.5	Acupuncture Needling Sensation Questionnaire	60
	5.3.6	Adverse reactions/events	61
	5.3.7	HCV/TCM pattern identification	61
		5.3.7.1 Baseline TCM pattern expression by all participants (treatment and control groups)	62
		5.3.7.2 Primary TCM patterns at baseline	64
		5.3.7.3 Secondary TCM patterns at baseline	64
		5.3.7.4 Tertiary TCM patterns at baseline	65
		5.3.7.5 Comparison of the primary, secondary and tertiary TCM patterns at baseline	66
		5.3.7.6 Comparison of the primary, secondary and tertiary TCM patterns at baseline and on completion of treatment	66
		5.3.7.7 Individual participant comparison of TCM pattern expression	70
Chapter 6	Discussion		71
Chapter 7	Conclusion		78
References			79

Page Number

Appendices

1.	Comprehensive report on HCV risk factors/transmission, the current Australian profile, Australian snapshot and epidemiology	89
2.	Activity Sequencing and Gantt chart	96
3.	Information sheet and brochures	101
4.	Recruitment Strategy	105
5.	Consent form	122
6.	HCV/TCM Pattern Questionnaire	124
7.	TCM Hepatitis Acupuncture Treatment Protocol	133
8.	QoL Questionnaire	135
9.	Acupuncture Treatment Credibility Questionnaire	140
10.	Acupuncture Needling Sensation Questionnaire	142
11.	TCM/Hepatitis Disease Patterns	145
12.	Individual comments to "What are your reasons for believing this?"	148
13.	Individual participant's baseline TCM pattern expression minus on completion expression graphs	149

Figures

		Page Number
Figure 2.1:	HCV prognosis and progression	8
Figure 2.2:	Global genotype/subtype distribution pattern	9
Figure 2.3:	Australian genotype profile (percent)	10
Figure 3.1:	A flowchart illustrating the process of reference exclusion	17
Figure 4.1:	CONSORT flow diagram showing recruitment, enrolment and randomisation	28
Figure 4.2:	Nonacupoint locations	33
Figure 4.3:	Outcome measure collection points	34
Figure 4.4:	Example of first three sensations of the Acupuncture Needling Sensation questionnaire	38
Figure 4.5:	Example of a HCV TCM pattern percentage graph for an individual	44
Figure 4.6:	HCV TCM pattern expression for an individual baseline (week 0) and at completion of the treatment (week 12)	45
Figure 5.1:	Flowchart of participants who did not continue to meet eligibility criteria during the trial	49
Figure 5.2:	Mean ALT levels for treatment and control groups at week 0 (baseline), 12 week (completion of treatment), weeks 16 and 20 (follow up periods)	50
Figure 5:3:	ALT levels for each subject in the treatment group at week 0 (baseline), week 12 (completion of treatment) and at weeks 16 and 20 (follow up periods)	51
Figure 5.4:	ALT levels for each subject in the control group at week 0 (baseline), week 12 (completion of treatment) and at weeks 16 and 20 (follow up periods)	51
Figure 5.5:	Individual participant viral load results at baseline and on completion for the treatment group	53
Figure 5.6:	Individual participant viral load results at baseline and on completion for the control group	53

Page Number

Figure 5.7: Mean scores for QoL domains for the treatment and control group across 20 weeks. Significant difference between the two groups at baseline are indicated * $p<0.05$, + $p<0.1$ 55

Figure 5.8: Mean ranks for the treatment and control group for each of the four questions administered at weeks 2, 6 and 12. Significant difference between the two groups is indicated * $p<0.05$ 58

Figure 5.9: Pattern expression percentage change for the primary patterns for the treatment and control group 68

Figure 5.10: Pattern expression percentage change for the secondary patterns for the treatment and control group 69

Figure 5.11 Pattern expression percentage change for tertiary patterns for the treatment and control group 70

Tables

		Page Number
Table 3.1:	Summary of five studies in the review	18
Table 4.1:	Location description of nonacupoints	32
Table 4.2:	Sham point selection schedule	32
Table 4.3:	Questionnaire administration intervals	38
Table 4.4:	Additional acupuncture symptom points	41
Table 4.5:	Example of symptom/signs associated with two TCM patterns of *liver yin vacuity* and *binding depression of liver qi*. Coloured block indicates symptom was present	42
Table 4.6:	TCM HCV scores for a trial participant	43
Table 5.1:	Participants' gender, age, whether they had previously received combination therapy and alcohol intake	48
Table 5.2:	Mean ALT (U/L) levels for the treatment and control groups at week 0 (baseline), week 12 (completion of treatment) and at weeks 16 and 20 (follow up periods)	50
Table 5.3:	Mean HCV PCR (viral load) IU/mL levels for the treatment and control group	52
Table 5.4:	Participant response to which intervention they received	59
Table 5.5:	Number of participants who had previously experienced acupuncture	60
Table 5.6:	Mean ranks and *p* values for the treatment and control group for the Acupuncture Needling Sensation Questionnaire administered (weeks one, four, eight and twelve)	61
Table 5.7:	The TCM patterns expressed by all participants at week 0 (baseline). Each participant is represented by their ID number	63
Table 5.8:	The primary HCV TCM pattern expression and mean percentage score of all participants (n=16) at week 0 (baseline)	64
Table 5.9:	The secondary HCV TCM pattern expression and mean percentage score of all participants (n=16) at week 0 (baseline)	65

Page Number

Table 5.10: The tertiary HCV TCM pattern expression and mean percentage score of all participants (n=16) at week 0 (baseline) 66

Table 5.11: The mean expression percentage for the primary, secondary and tertiary TCM pattern at baseline (week 0) and on completion of treatment (week 12) for the treatment and control group. *p* values are shown in bold where significant 67

Abbreviations - Acronyms

ANOVA	Analysis of Variance
ALT	Alanine Aminotransferase
AGDHA	Australian Government Department of Health and Ageing
AST	Aspartate Aminotransferase Tests
CAM	Complementary and Alternative Medicine
CHC	Chronic Hepatitis C
CHM	Chinese Herbal Medicine
CONSORT	Consolidated Standards of Reporting Trials
EIA	Enzyme immunoassays
ELISA	Enzyme linked immunosorbent assay
HBV	Hepatitis B Virus
HCC	Hepatocellular carcinoma
HCCNSW	Hepatitis C Council of NSW
HCV	Hepatitis C virus
HCVPWG	Hepatitis C Virus Projections Working Group
HIV	Human immunodeficiency virus
HREC	Human Research Ethics Committee
ID	Identification Number
IDU/s	Injecting drug user/s
IFN	Interferon alpha
IU	International Unit (measurement)
LFT	Liver Function Test
m/L	Millilitre
NCHECR	National Centre in HIV Epidemiology and Clinical Research
NSP	Needle and syringe program
PCR	Polymerase Chain Reaction
PBS	Pharmaceutical Benefits Scheme
QoL	Quality of Life questionnaire
RCT	Randomised Controlled Trial

RNA	Ribonucleic acid
SF36	Short Form 36 Health Survey Questionnaire
SF-36v2	Short form 36 version 2 Questionnaire
TCM	Traditional Chinese Medicine
U/L	Units per Litre
UTS	University of Technology, Sydney

Abstract

Background

The use of Complementary and Alternative Medicine (CAM) in Australia has been steadily increasing. This has resulted in many people infected with Hepatitis C Virus (HCV) consulting CAM practitioners in the hope of alleviating some of the debilitating symptoms associated with this viral infection. Chronic symptoms often lead to a reduction in everyday functional health producing a lower quality of life compared with healthy population norms or patients with other forms of liver disease. Current recommended pharmaceutical treatment has a sustained virological response in approximately 50-60% of patients. Also large numbers of people are either not suitable candidates or intolerant to treatment or do not choose this option.

In the mid 1990s, HCV residents in a Sydney alcohol and drug rehabilitation centre who were also receiving auricular (ear) acupuncture as part of their rehabilitation program, verbally reported decrease in their alanine aminotransferase (ALT) blood levels after approximately 16 acupuncture treatments administered over a three month period (Berle 1997).

Objective

To investigate whether 24 acupuncture treatments over a twelve week period has an effect on the health outcomes of people with HCV.

Design

A randomised single blind controlled pilot study with two parallel arms.

Participants

Sixteen applicants who met the eligibility criteria and agreed to participate in the study were randomised into either treatment or control group.

Outcome measures

The primary outcome measure was ALT blood levels at the completion of treatment (week 12), weeks 16 and 20. The secondary outcomes were HCV PCR quantitative (viral load test) and hepatitis quality of life (QoL) questionnaire. In addition a HCV Traditional Chinese Medicine (TCM) pattern questionnaire, acupuncture treatment credibility questionnaire and acupuncture needling sensation questionnaire were administered.

Setting

Participants were offered treatment at two clinic locations; a private clinic at Guildford and at the University of Technology, Sydney (UTS) city campus. Blinded serum pathology/testing was conducted through independent Douglass Hanly Moir Pathology clinics.

Treatment

Sixteen HCV participants were randomly allocated to two groups; one group receiving verum acupuncture treatment and the other receiving invasive sham acupuncture treatment. The treatment methodology involved the development of a TCM pattern differentiation diagnostic/outcome measure which identified 17 TCM/HCV patterns.

One participant (treatment group) left the study after eight treatments due to work commitments.

Results

No significant change was found between the two groups for ALTs, viral load or any domains of the QoL measure.

The TCM pattern questionnaire identified the primary, secondary and tertiary TCM pattern expressions for HCV within the study group. On completion of the treatment phase there was a significant reduction in the secondary and tertiary TCM pattern expression for the treatment group ($p=0.045$ and 0.037 respectively). No significant change was found for the control group.

The acupuncture credibility questionnaire identified that neither the treatment nor control group identified the type of treatment they had received; however the treatment group did perceive their treatment as more credible than the control group at week 12. There was no significant difference found between or within the two groups for the acupuncture needling sensation questionnaire.

Conclusions

Despite the small number of participants and no significant changes for ALTs, viral load or any domains of the QoL there was a significant difference in the secondary and tertiary TCM patterns.