

INEBRIA meeting
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On-line randomized controlled trial of an Internet based psychologically enhanced intervention for people with hazardous alcohol consumption (DYD RCT)

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NPRI

Alcohol - the size of the problem

- Hazardous alcohol consumption associated with 3.8% of global deaths
- 4.6% global disability-adjusted life years
- EU is heaviest alcohol drinking region in world
- In UK, deaths from cirrhosis are rising up to x10
- Good evidence about effectiveness of brief interventions in primary care, but only minority receive help
- In UK, fewer than 1 in 18 people with alcohol use disorder access appropriate treatment

Internet based interventions and psychological enhancement

- Increased population access to Internet: 77% UK, 64% in EU and 74% in US (2009 figures)
- Growing evidence about ability of Internet to deliver effective smoking interventions
- Psychological enhancement (tailored behavioural techniques) associated with improved knowledge, self efficacy, perceived social support, health behaviours and clinical outcomes

DYD RCT

- Phase 3 two arm RCT conducted entirely on-line
- Comparison between psychologically enhanced intervention and minimally interactive comparator
- Key methodological issues:
 - Sustainability of on-line recruitment
 - Compliance with the intervention
 - Anticipated low follow-up rates



NPRI

DYD RCT hypotheses:

Subjects randomised to access to psychologically enhanced site will:

- exhibit lower levels of consumption
- demonstrate lower levels of alcohol dependence
- report lower levels of alcohol related harm and social disruption
- report improved quality of life
- experience cost benefits exceeding those of face to face interventions

Outcome measures

- **Primary:**
 - TOT-AL – previous 7days' drinking
 - EQ-5D (well being)
- **Secondary:**
 - Alcohol Use Disorders Test (AUDIT)
 - Alcohol Problems questionnaire (APQ)
 - Leeds Dependence questionnaire (LDQ)
 - Clinical Outcomes in Routine Evaluation Outcome Measures (CORE)

Recruitment and follow-up

- Trial undertaken in three phases:
 - Pilot : FU 1m and 3m
 - Main trial: FU 3m and 12m
 - Main trial extension: FU 3m
- Recruitment via the entry pages of the DYD website
- Inclusion: all patients aged 16 + who scored 4 or more on AUDIT-C
- On line consent form and randomisation

Maximising questionnaire response at 3 months and 12 months

- FU requirements explicit in consent procedure
- email prompts and reminders to complete questionnaires
- request for “terrestrial” co-ordinates in order to make direct contact
- incentives for participation (prize draw)

Statistical methods

- Pre-specified statistical analysis plan
- 430 participants with complete data per arm to give 90% power at 5% significance to detect 20% reduction in past week's alcohol consumption.
- Primary analysis without imputation missing values
- Additional analyses using LOCF and multiple imputation for missing values
- Complier-average causal effect (CACE) analysis to estimate effect of compliance with intervention
- Final analysis undertaken on data pooled from all 3 phases



DYD entry portal

USER NAME:

REMINDER

PASSWORD:

LOG IN

SEARCH SITE:

GO

ABOUT US



▶ How's Your Drink?

Most of us drink. Some of us drink more regularly than others. But how often is too often? And how much is too much?

The fact is, alcohol affects all of us differently. What is manageable for some can be a problem for others. Remember, drinking regularly may not mean you have a serious problem. It may only take a small change to make a big difference.

This site is designed to help you work out whether you're drinking too much, and if so, what you can do about it.

Find out if you are drinking too much



AUDIT-C entry test

USER NAME:

PASSWORD:

LOG IN

[HOME](#) | [ABOUT US](#)

The test

1 drink = 1/2 pt beer or 1 glass of wine or 1 single measure of spirits.

How often do you have a drink containing alcohol?

- Never Monthly or less 2-4 times a month 2-3 times a week 4 or more times a week

How many drinks containing alcohol do you have on a typical day when you are drinking?

- 1 or 2 3 or 4 5 or 6 7 to 9 10 or more

How often do you have six or more drinks on one occasion?

- Never Less than monthly Monthly Weekly Daily or almost daily

Submit »



Feedback on AUDIT

SEARCH SITE:

[HOME](#) | [ABOUT US](#)

Results

★ Thank you for taking the test, your **drinking pattern indicates a possible increased risk of alcohol affecting your health.**

★ The **new Down Your Drink** website is packed full of useful information designed to help people **drink alcohol more safely** and improve their general health and well-being.

Would you like to use Down Your Drink, and help us with our research evaluating how well the website works?

Yes

No

Important Announcement!

[Alcohol Concern](#) and the [Medical Research Council](#) have commissioned a **major new research study** to test scientifically if the new website could have an **important benefit** for people like you and the community.

Learn more about the research team >> [click here](#)





Invitation to participate

SEARCH SITE:

[HOME](#) | [ABOUT US](#)

Your invitation to take part in the study

Can you help us with our research?



- You should be aged **18 years old or over** and able to read and write English.
- You **need to be willing** to spend **around 30 minutes now to fill in some forms online** and **again in 1 month's time**

If you would like to use DYD and help us with our research, please click "still interested" above



Intervention site

USER NAME: REMINDER
PASSWORD: LOG IN
SEARCH SITE: GO

- Home
- Contact
- My record
- My Goals
- My Drinking Diary
- Tools
- Library
- Links

PANIC BUTTON!

- PHASE 1 IT'S UP TO YOU
- PHASE 2 MAKING THE CHANGE
- PHASE 3 KEEPING ON TRACK

Welcome

A "three phase a useful informatio Please treat this

We recommend t [How to Use this](#)

- Motivational enhancement
- Making the change
- Relapse prevention

PHAS Its up to



This phase is des help you make up about whether the anything you mig change about your drinking.

» [Start](#)

» [Start](#)

» [Start](#)

Psychological enhancement features

- Tailored feedback
 - E-tools (consumption calculator, diaries/self-report)
- Automated and tailored emails (reminders to log on, tips)
 - On-line quizzes
- Interactive graphics
 - “Thinking drinking record”
- Interactive tools for setting change date(s)

We record
[How to U](#)

P H

It



This phase is designed to help you make up your mind about whether there is anything you might want to change about your drinking?

You have made a decision to change your drinking and a plan for how to do it . Phase 2 provides some additional support as you do it.

This phase is about learning skills to help you stick to your goals and make changes to your lifestyle.



Comparator site

[LOG OUT DANNY BERZON»](#)

- Home
- Library
- Links
- News

Welcome to Down Your Drink. This is a website designed to give you information about the effects of alcohol...

- **Minimally interactive**
- **Information pages**
 - The facts
 - The signs,
 - Healthy living
 - Getting help
 - Help a friend

Contents

- ▶ [The Signs](#)
- ▶ [The Facts](#)
- ▶ [Healthy Living](#)
- ▶ [Getting Help](#)
- ▶ [Help a Friend](#)

- **Library**
- **Links**
- **News**



Recruitment to trial over 3 phases



Baseline characteristics: demographics

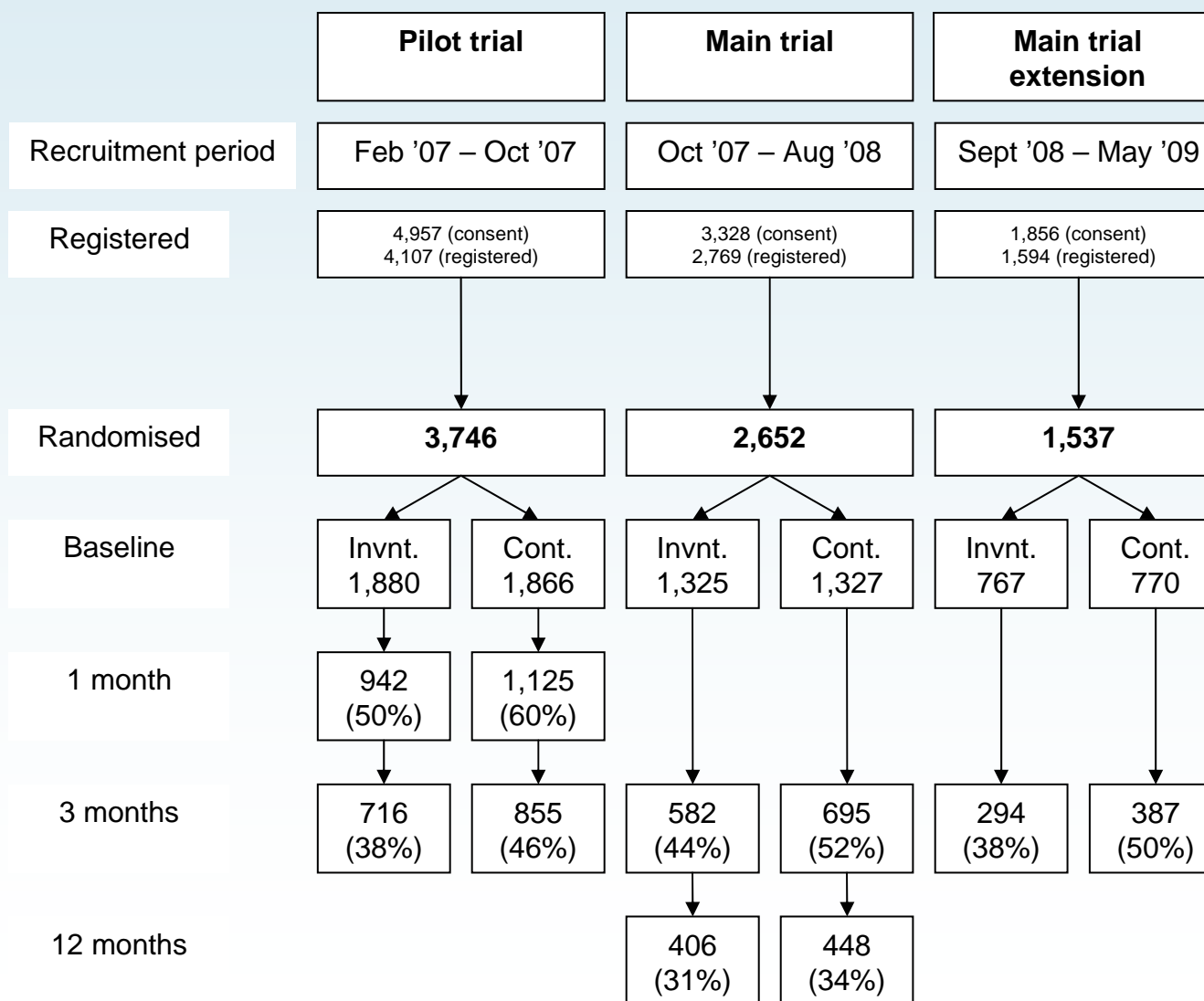
n = 7,935

Age	Mean 38, (18 – 93)
Gender	58% female
Education	51% university degree or above
Marital status	62% married or long term relationship
Children	51% 1 or more children
Ethnicity / country	83% White British / 88% UK residents Respondents from total of 73 countries

Baseline characteristics: clinical

by randomised group	Intervention	Control
AUDIT-C: mean (SD)	8.51 (2.02)	8.49 (2.02)
Past week's alcohol consumption (TOT-AL) (Geometric mean and approx. SD)	46.3 (31.8)	45.7 (30.6)
Maximum units consumed in any one day (Geometric mean and approx. SD)	15.8 (9.5)	15.6 (9.5)
Number of drinking days: mean (SD)	5.0 (1.9)	5.0 (1.9)
Number of drinking days drinking above recommended limits (2+ ♀, 3+ ♂) units of alcohol: mean (SD)	4.8 (1.9)	4.8 (1.9)
Number of days drinking 6+ (♀), 8+ (♂) units of alcohol: mean (SD)	3.6 (2.2)	3.5 (2.1)
EQ5D: mean (SD)	0.84 (0.19)	0.84 (0.19)
Health state meter: mean (SD)	66.6 (23.6)	66.5 (23.4)
Self-efficacy score: median (IQR) 0: low, 5: high	3 (2)	3 (2)
Intentions score: median (IQR) 0: low, 5: high	4 (2)	4 (2)
Audit: mean (SD)	18.8 (7.4)	18.7 (7.2)
APQ: mean (SD)	6.6 (4.3)	6.7 (4.2)
LDQ: mean (SD)	9.1 (5.8)	8.7 (5.5)
CORE-OM: mean (SD)	1.3 (0.7)	1.3 (0.7)
CORE-10: mean (SD) Main and extension	16.3 (4.9)	16.6 (5.0)

CONSORT diagram showing pilot, main trial and main trial extension



Number of website sessions and pages downloaded at 3 months by randomised group

Randomisation group	Phase 1 N=3,746	Phase 2 N=2,652	Phase 3 N=1,537
Website Sessions			
Intervention	2.24 (3.28)	2.32 (3.90)	2.57 (3.91)
Control	1.29 (0.84)	1.19 (0.69)	1.18 (0.62)
Both groups	1.77 (2.45)	1.76 (2.86)	1.88 (2.88)
Pages downloaded			
Intervention	63 (68)	64 (67)	73 (73)
Control	13 (13)	13 (12)	12 (11)
Both groups	38 (55)	39 (54)	42 (60)

Secondary outcome measures

Intervention vs control at 3m - mean (SD)

	Intervention	Control
EQ-5D	0.87 (0.2)	0.88 (0.2)
AUDIT	15.2 (8)	15.6 (7)
APQ	4.0 (4)	4.3 (4)
LDQ	6.7 (5)	6.1 (5)
CORE-10	14.5 (4)	14.9 (4)

Reported weekly alcohol consumption (units) by randomised group

Time point	Geometric mean (SD)		Adjusted ratio (intervention : control) of geometric means (95%CI)
	Intervention	Control	
Baseline (n=7,935)	46.3 (31.8)	45.7 (30.6)	-
1 month (n=2,067)	27.1 (23.1)	27.1 (22.5)	0.98 (0.90 to 1.07)
3 months (n=3,529)	26.4 (23.0)	25.6 (21.5)	1.03 (0.97 to 1.10)
12 months (n=854)	22.0 (20.0)	23.5 (21.0)	0.99 (0.85 to 1.15)

Secondary outcome measures intervention versus control at 3m - TOTAL

	Intervention	Control
No drinking days/week	4.15	4.18
No days > 2 / 3u	3.86	3.90
Max units in 1 day	11.24	10.91
No days > 6 / 8 u	2.32	2.51

Additional analyses

- Subgroup analyses - no impact of pre-specified baseline characteristics
- Sensitivity analyses for missing data and allowing for systematic differences between responders / non-responders - no evidence differential effect of intervention
- Little evidence of effect of website exposure

Summary of main findings

- On-line trial recruited large numbers
- Participants characterised by heavy consumption and significant harms but not dependence
- Follow-up rates low, (but better than expected)
- Large and clinically significant fall in alcohol consumption across both arms at 3m (c 21u / wk) sustained at 12 m (c 25 u/wk), with parallel improvement in secondary outcomes.
- No evidence to support hypothesis that psychological enhancement confers benefit

Discussion:

- Large scale pragmatic trial of alcohol Internet intervention
- However, poor follow up & compliance with intervention complicate interpretation.
- Striking improvements in both groups likely to be due in part to regression to mean, burden of assessment, Hawthorne effect, selection bias - “eHealth seekers”
- No evidence of advantage of psychological enhancement - possible failure to reach threshold exposure
- Further research underway on potential to increase website engagement through facilitation in primary care and other settings

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- DYD RCT Trial Steering Group (Chair Prof Sir Andy Haines)

- NPRI
- AERC
- Alcohol Concern