fuse The Centre for Translational Research in Public Health

Com-BI-ne: Final results of a feasibility trial of brief intervention to improve alcohol consumption & co-morbid outcomes in hypertensive or depressed primary care patients

GB Wilson[1], *C Wray*[1], *R McGovern*[1], *D Newbury-Birch*[1], *E McColl*[1], *A Crosland*[2], *C Speed*[1], *P Cassidy*[3], *D Tomson*[4], *S Haining*[5], *EFS Kaner*[1]

[1]Institute of Health & Society, Newcastle University; [2]Department of Pharmacy, Health & Well-being, Sunderland University; [3]Teams Medical Practice, Gateshead UK; [4]Collingwood Health Group, North Tyneside UK; [5]NHS North of Tyne

www.fuse.ac.uk

Background

Heavy drinking, the second greatest risk to public health in developed countries, affects many physical and mental health problems.[1,2]

Brief interventions (BIs) consisting of structured advice and counselling help patients reduce hazardous or harmful drinking by about 7 drinks each week,[3] but research has excluded patients diagnosed with other health problems.[4]

Many people with raised blood pressure and/or depression drink over medically recommended levels; reducing their alcohol consumption should improve symptoms of these conditions.[5,6]

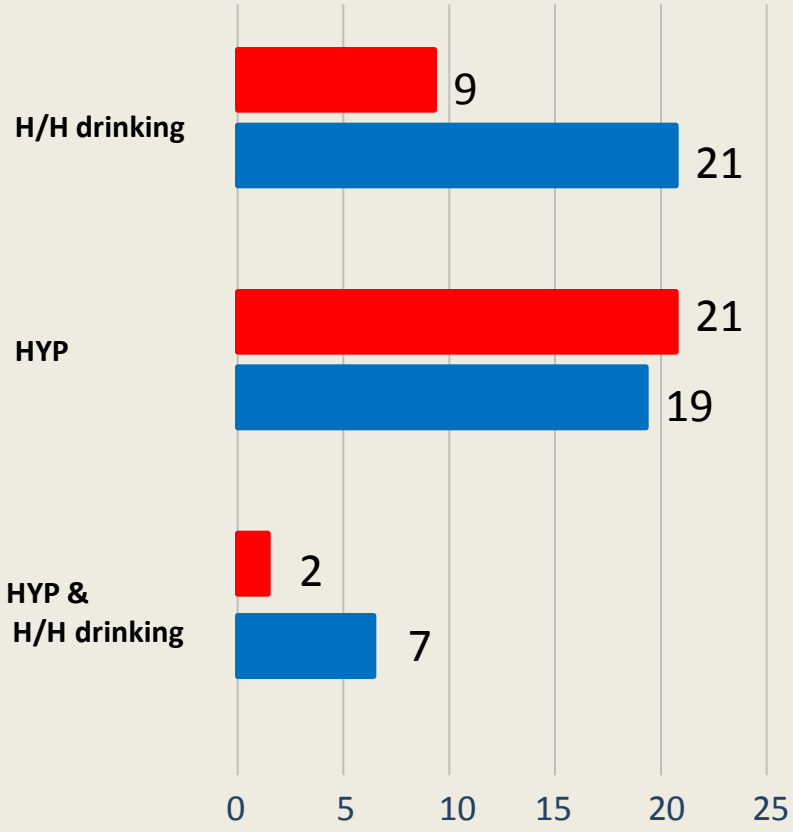
Com-BI-ne aims to assess the feasibility of conducting a definitive future RCT exploring BI in primary care for hazardous or harmful drinkers with co-morbid hypertension or depression.

fuse The Centre for Translational Research in Public Health

[1]World Health Organization. *Global Health Risks*. Geneva: WHO; 2009.
[2]Ezzati M, et al, *The Lancet*. 2002;360:1347-60.
[3]Kaner, E.F.S., et al. *Cochrane Database of Systematic Reviews*, 2007(2): p. CD004148.
[4]Whitlock EP, et al. *Am Jnl Prev Med*. 2002;22(4):267-84.
[5]Xin X, et al. *Hypertension*. 2001 Nov;38(5):1112-7.
[6]Manninen L, et al. *Alcohol & Alcoholism*. 2006 May-Jun;41(3):29

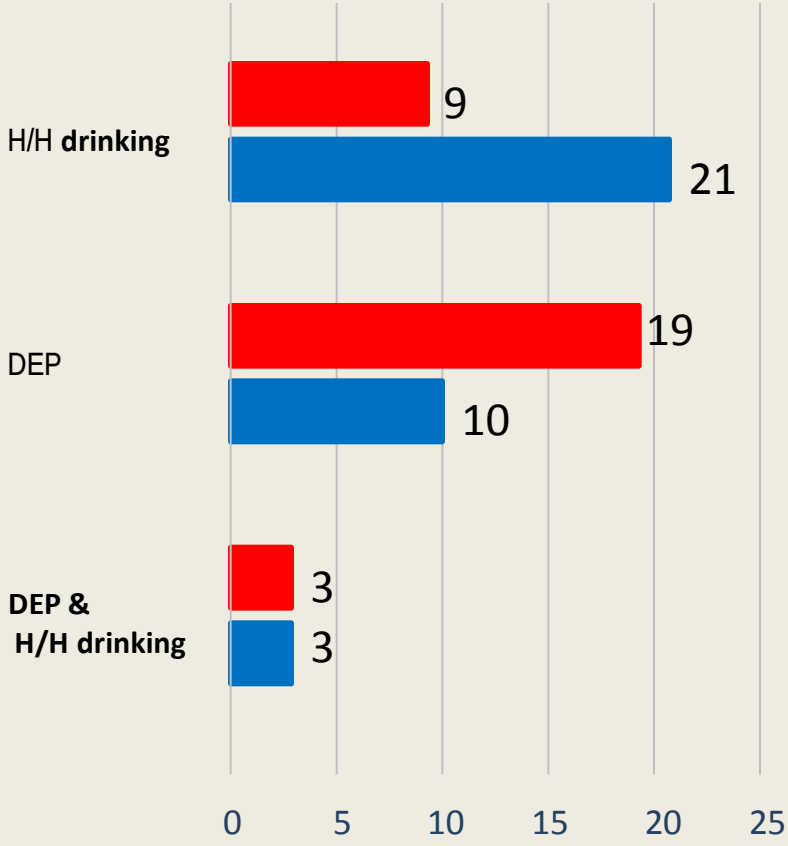
Prevalence of co-morbidities in North of Tyne

Rates of hazardous or harmful drinking and hypertension



Median % of adult patients at 25 GP practices

Rates of hazardous or harmful drinking and mild/ moderate depression



Median % of adult patients at 25 GP practices

Female
Male

H/H = hazardous/harmful

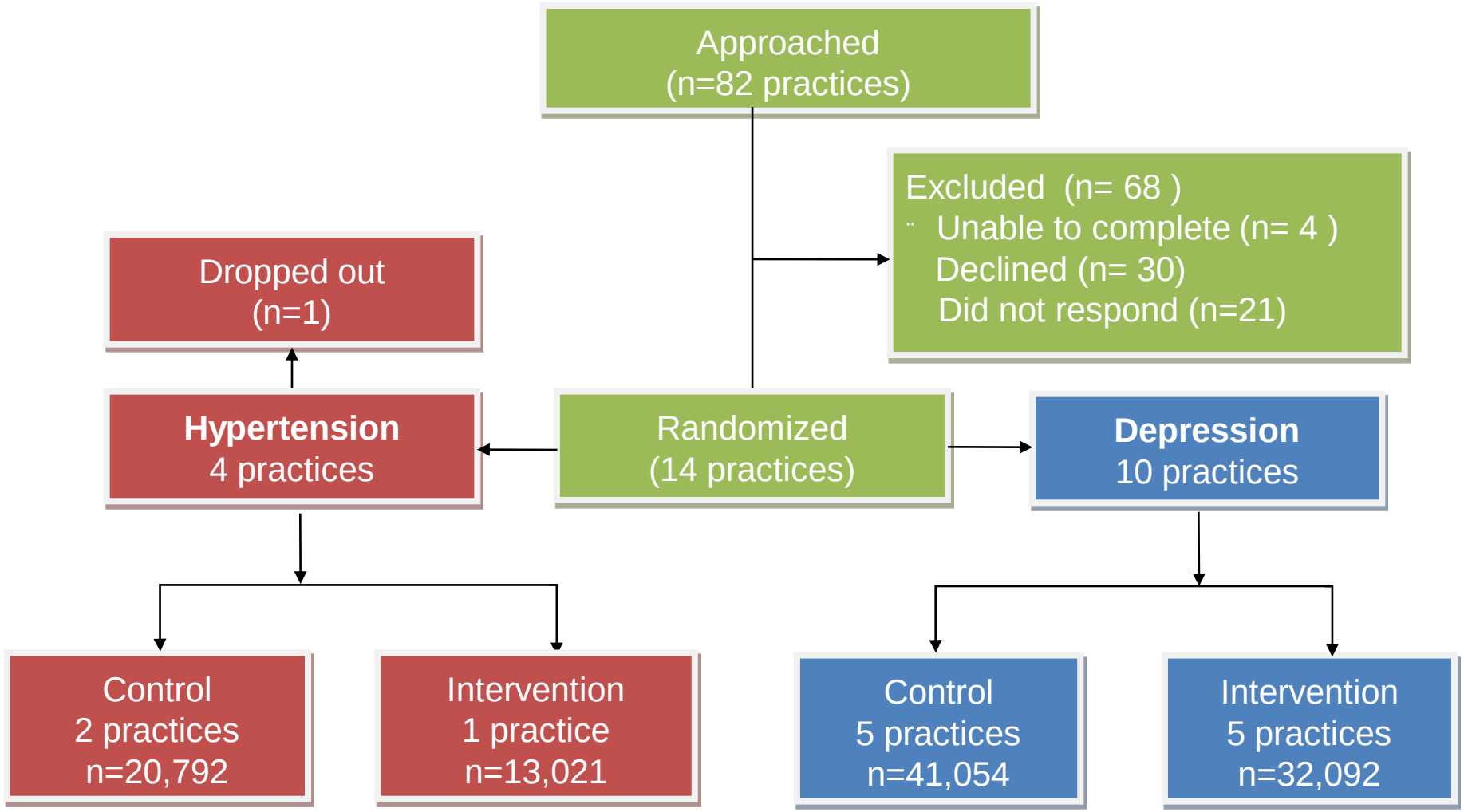
HYP = hypertension

DEP= mild/moderate depression

The Com-BI-NE trial - Method

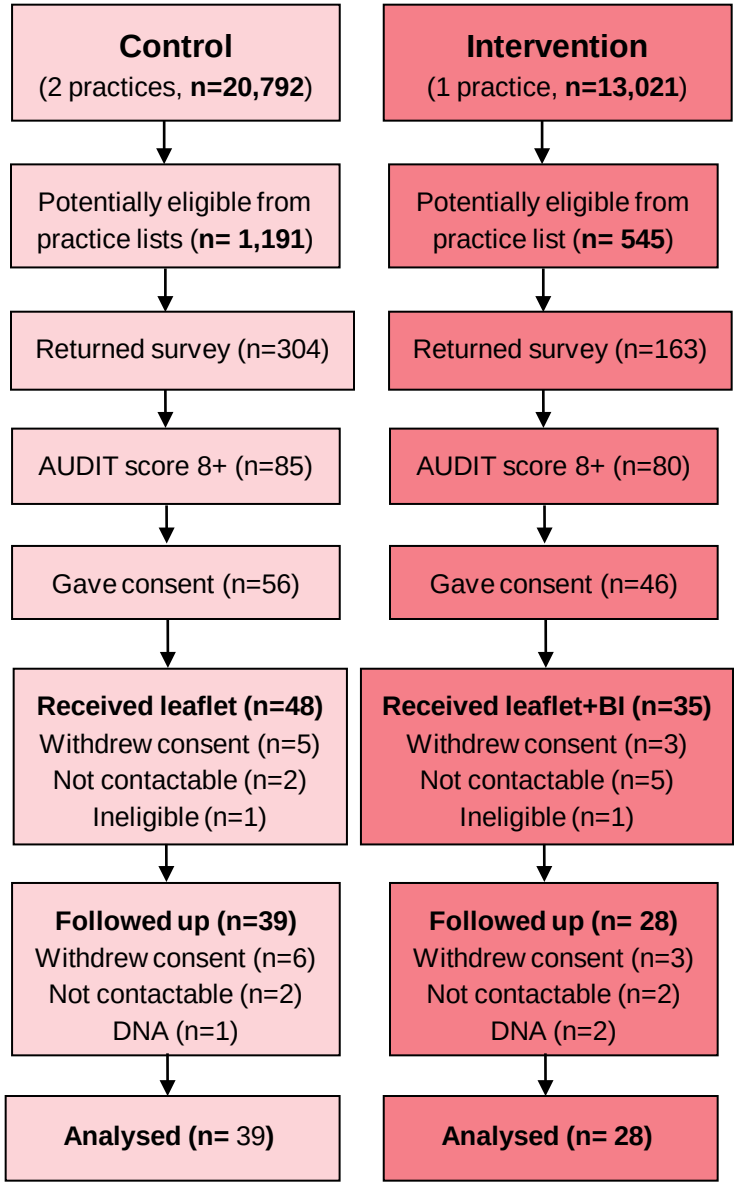
- GP practices randomised to hypertension or depression arm, then control or intervention condition. AUDIT screening tool for alcohol consumption was sent to all co-morbid adult patients.
- Consenting respondents scoring positively on AUDIT (>7) were screened for co-morbid conditions (PHQ-9 or blood pressure) & received brief intervention or patient information leaflet (control condition).
- After 6 months, follow-up screening for alcohol use and co-morbid condition was sought

Flow chart 1: Recruitment & allocation of GP practices



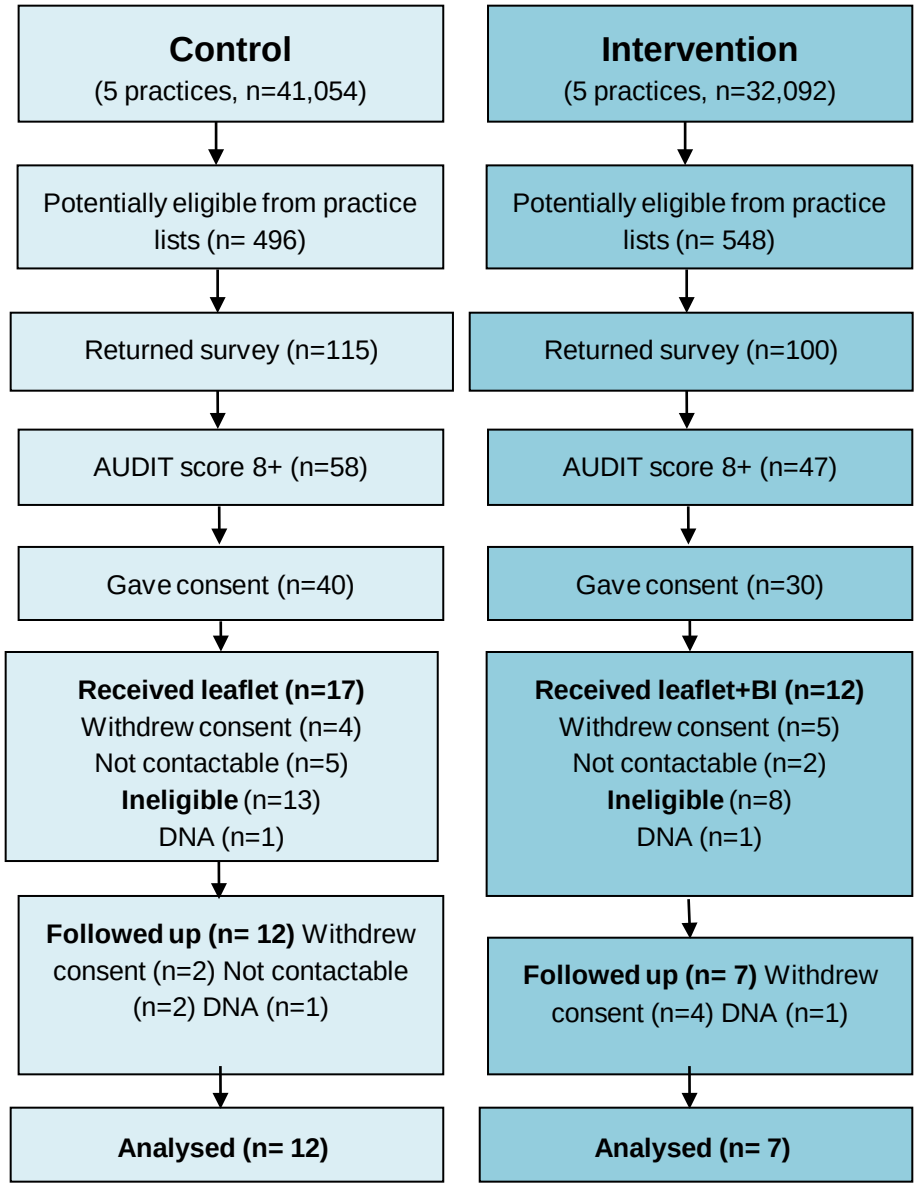
fuse The Centre for Translational Research in Public Health

Flow chart 2: Hypertension arm



fuse The Centre for Translational Research in Public Health

Flow chart 3: Depression arm



fuse The Centre for Translational Research in Public Health

Recruitment and retention rates

Of 1,709 potentially eligible patients in the hypertension arm:

- 27% returned a questionnaire
- 6% were fully eligible (scored 8+ on AUDIT-C & consented)
- 5% were recruited to the trial (81% of fully eligible)
- 4% were followed up at 6 months (81% of recruited)

Of 1,044 potentially eligible patients in the depression arm:

- 21% returned a questionnaire
- 6% were fully eligible (scored 8+ on AUDIT-C & consented)
- 3% were recruited to the trial (41% of fully eligible)
- 2% were followed up at 6 months (66% of recruited)

Recruitment and retention rates

Figures from the hypertension arm suggest that in a full trial:

- **2480** adult patient records would yield 100 eligible patients
- **2591** eligible patients would yield 100 cases at 6 months
- **64,257** adult patient records (**10 GP practice databases**) would need to be searched to achieve 100 cases enrolled and followed up at 6 months

Figures from the depression arm suggest that in a full trial:

- **3687** adult patient records would yield 100 eligible patients
- **5895** eligible patients would yield 100 cases at 6 months
- **217,348** adult patient records (**33 GP practice databases**) would need to be searched to achieve 100 cases enrolled and followed up at 6 months

Characteristics & baseline scores

hypertension (n=83) & depression (n=29) cases

	Hypertension				Depression			
	n	Control	Intervention	p	n	Control	Intervention	p
Mean age in yrs (sd)	81	63 (8.1)	66 (10.4)	0.239	29	53 (13.3)	50 (16.2)	0.639
% male	83	90	86	0.593	29	65	75	0.555
% not in paid employment	78	77	71	0.503	26	50	70	0.315
Mean AUDIT (sd)	83	12 (4.7)	12 (4.7)	0.906	29	15 (6.4)	20 (9.7)	0.111
PHQ-9	-	-	-	-	29	10 (4.2)	11 (4.7)	0.632
Systolic BP	83	153 (19.4)	149 (16.1)	0.412	-	-	-	-
Diastolic BP	83	88 (10.1)	87 (8.8)	0.787	-	-	-	-

Outcome measures over time

hypertension (n=83) & depression (n=29) cases

	Hypertension			Depression		
	Intervention (n=28)	Control (n=39)	Difference between means (95% CI)	Intervention (n=7)	Control (n=12)	Difference between means (95% CI)
	Mean change T2-T1 (SD)	Mean change T2-T1 (SD)		Mean change T2-T1 (SD)	Mean change T2-T1 (SD)	
AUDIT score	-1.8 (2.92)	-1.5 (5.2)	0.3 (-1.9 to 2.5)	-3.1 (4.9)	-1.5 (5.0)	1.6 (-3.3 to 6.6)
Systolic BP	-2.0 (17.7)	-3.2 (16.8)	-1.2 (-9.7 to 7.3)	-	-	-
Diastolic BP	2.2 (10.62)	1.8 (9.12)	0.4 (-4.5 to 5.4)	-	-	-
PHQ-9 score	-	-		-2.9 (5.7)	-0.7 (6.1)	2.2 (-3.8 to 8.2)

Summary of findings

In the hypertension arm, 4% of co-morbid adult patients could be identified as eligible and 5% recruited as cases, 81% of whom were followed up at 6 months.

In the depression arm, 3% of adult patients could be identified as eligible. 2% of eligible patients were recruited as cases, 66% of whom were followed up at 6 months.

Outcome measures for a full trial other than blood pressure showed greater improvement in intervention than control, though not statistically significant, at 6 month follow-up.

The research tasks were not perceived as burdensome by practices or patients.

❖**RCT with patients suffering from hypertension and drinking heavily appears feasible**

Explaining findings

Higher recruitment & retention in the **hypertension** arm may be due to:

- Older sample – more available & visiting GP surgery more often
- Mostly male sample – likelier to admit heavy drinking, though less likely to attend GP
- Physical condition with little stigma attached (Well Man/Woman clinics)

But:

- Participants seemed more sceptical of connection between condition and heavy drinking
- BP outcome measures were highly variable and direction of change contradictory

Explaining findings

Lower recruitment and retention in **depression** arm may be due to:

- Younger sample – more likely to be at work, see GP less often
- More female participants – greater stigma around heavy drinking
- Mental health condition – stigmatised, less likely to attend appointments

But:

- Patients readier to acknowledge connection between condition and heavy drinking
- Recording of depression on GP databases variable[7]

❖ Eligibility criterion for depression (PHQ score 5-19 at recruitment) led to lower rate of cases from fully eligible respondents in the depression arm **(41%)** cf hypertension arm (**81%**).

❖ Many patients who were excluded at baseline appointment described fluctuating condition that PHQ-9 may not capture[8]

fuse The Centre for Translational Research in Public Health

[7]Mitchell et al. Clinical recognition and recording of alcohol disorders by clinicians in primary and secondary care: meta-analysis. *B J Psychiatry* 2012; **201**; 93-100.
[8]Malpass et al. Concordance between PHQ-9 scores and patients' experiences of depression. *BJGP* 2010; DOI 10.3399/bjgp10X502119.

Conclusions

- A protocol will be developed for a full trial of BI to reduce alcohol consumption in patients with co-morbid hypertension and excessive alcohol consumption
  - Recent developments in 24 hr/home BP measurements[9,10] can address variability of one-off measurements

- Alternative approaches are being considered for a trial around co-morbid mild/moderate depression and AUD:
  - Universal screening for alcohol
  - Alternatives to single PHQ-9[11] as eligibility criterion and outcome measure

fuse The Centre for Translational Research in Public Health

[9]Parati et al. ESH guidelines for BP monitoring at home. *J Hyp* 2008; **26**; 1505-1530
[10]Warren et al. Variability of office, 24-hr ambulatory & self-monitored BP measurements. *BJGP* 2010, **60**; 675-680
[11]Moore et al. Depression management in primary care. *BJGP* 2012; **62**; 310-311

Acknowledgements

The Com-BI-ne trial is funded by NHS North of Tyne

NHS North of Tyne

The work was undertaken by Fuse, a UKCRC Public Health Research: Centre of Excellence. Funding from the British Heart Foundation, Cancer Research UK, Economic and Social Research council, Medical Research Council, and the National Institute for Health Research, under the auspices of the UK Clinical Research Collaboration, is greatly acknowledged.

Opinions expressed in this presentation do not necessarily represent those of the funders.