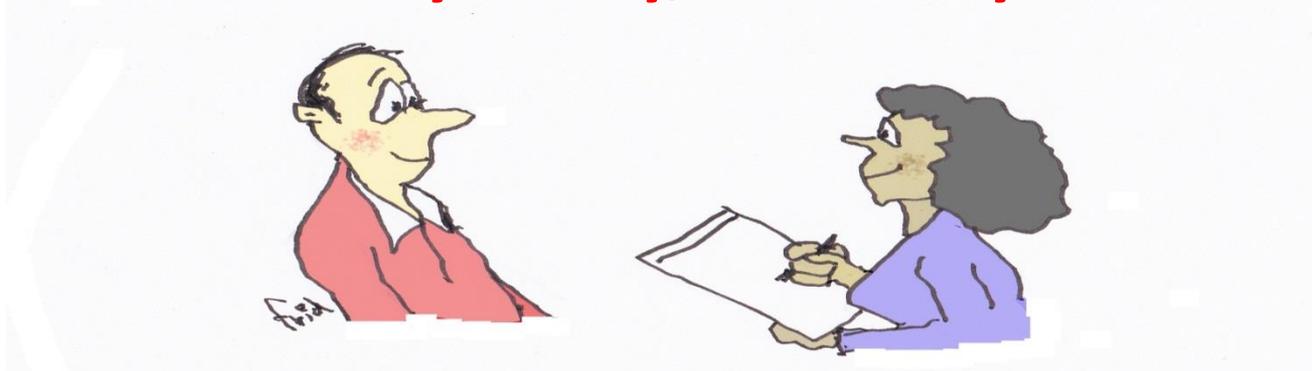


Multi-centre randomised controlled trial (RCT) for health anxiety in primary and general hospital care: clinical and economic outcomes.

**Richard Morriss,
Professor of Psychiatry, University of Nottingham**



The University of
Nottingham

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A partnership between
Nottinghamshire Healthcare Foundation
NHS trust and the
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University of
Leicester

Research Team

- Richard Morriss, Shireen Patel, Sam Malins, Boliang Guo, Fred Highton, David Waldram, Marilyn James, Mengjun Wu, Paula Brown, Naomi Boycott, Catherine Kaylor-Hughes, Martin Morris, Emma Rowley, Jayne Simpson, David Smart, Michelle Stubbley, Joe Kai, Helen Tyrer.

Background: Unscheduled care

- Unscheduled same day care in health services = any unplanned contact with health service by a person seeking help, care or advice.
- Escalating problem across the world.
- Severe health anxiety is one of the most common reasons for repeat unscheduled same day care

Background: severe health anxiety

- Severe health anxiety (SHA) can lead to increased unscheduled care use:
 - a) for reassurance and increased medical investigations,
 - b) delayed healthcare attendance followed by catastrophic emergency presentation because of anxiety-related healthcare avoidance.

Background: engagement

- Many high utilisers of unscheduled health care do not recognise that they have a mental health problem, let alone SHA.
- In such patients, mental health problems are stigmatised.
- Doctors and nurses do not routinely tell such patients they have health anxiety.
- They do not go to existing NHS psychological services e.g. IAPT.

Underpinning Patient and Public Involvement and clinical work

- Previous CLAHRC EM study developing CBT for long-term frequent attenders in primary care (Malins et al, 2016).
- CBT halved resource use over 12 months but only 7% willing to accept face to face CBT at practice.
- **Network of practice:** researchers, people with health anxiety, GPs and hospital clinical staff including CBT therapists met before and iteratively through the project.

Network of practice

- Referral from clinical staff e.g. GP, A and E staff, hospital specialist.
- Non-stigmatising words: *“the study wished to find out if talking to a health professional via videoconferencing or the telephone might help patients cope better with distress linked to their bodily symptoms.”*
- Remote therapy (before COVID-19) because going to see a therapist was too intimidating – can leave more easily by switching off video or putting phone down.

Implementability into practice

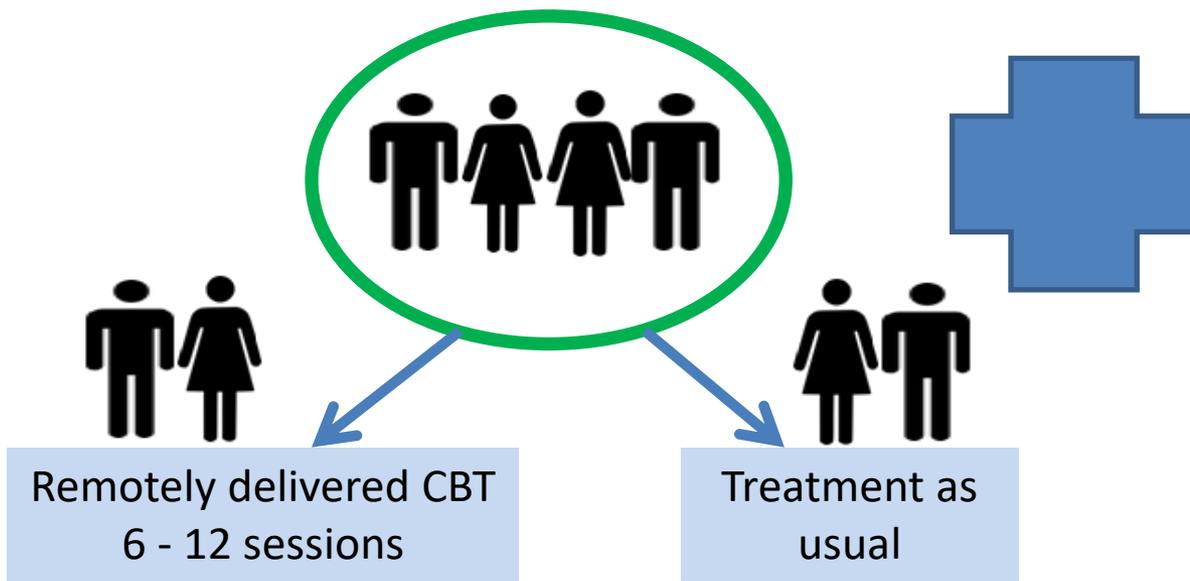
- NHS moving towards Integrated Care Systems so that local NHS organisations co-operate rather than compete with each other.
- Resources considered across a health care system not just in service budgets, allowing spend in one budget to save in another.
- Policy priority – reduce same day care and unnecessary hospital /emergency use.
- Greater familiarity with digital and remote therapy.
- CBT for SHA is a core competency for IAPT CBT staff.
- CBT promotes self-help so effects may be sustainable.

Aims of the Study

- 1. Compared to usual care, is CBT offered to repeat users of unscheduled care with SHA via video calling or phone effective?**
 - Relieving distress (primary outcome health anxiety 6 months)*
 - Improving overall physical and emotional health over 12 months*
- 2. Is it cost saving or cost effective over 12 months?**
- 3. Does it engage a high proportion of eligible pts?**

Methodology: Design

**Randomised Controlled Trial:
single blind (n=156)**



**Two Doctoral
research projects:**

i) Investigating the enablers and barriers to the implementation of the study

ii) Factors contributing to the optimisation of therapy

Study Setting

Participants recruited from primary and secondary care in East and West Midlands and West Yorkshire:

- GP practices
- Out of Hours Care
- Walk-in centres
- Emergency Departments
- Hospital out-patients (acute hospital, not mental health)

Recruitment is a two stage process. Initial approach is by clinicians.

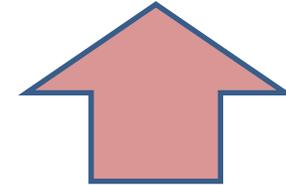
Inclusion/Exclusion criteria

Inclusion Criteria



- Aged 18 and over
- ≥ 2 attendances at any provider of unscheduled, urgent or emergency care in last 12 months
- Attendances for symptoms not attributed to identified pathology
- ≥ 18 on Health Anxiety Inventory

Exclusion criteria



- Pathological medical condition requiring further assessment or acute management
- Other severe mental illness
- Organic mental disorder
- Received specialist mental health intervention in the last 6 months
- Significant learning disability

Outcome measures (0,3,6,9,12 months)

SHAI	14-item Short Form Health Anxiety Inventory (Salkovskis et al., 2002).
PHQ-9	Patient Health Questionnaire for Depression (Kroenke, Spitzer & Williams, 2001).
GAD-7	Generalised Anxiety Disorder (Kroenke, Spitzer & Williams, 2006).
PHQ-15	Patient Health Questionnaire for Somatic Symptoms (Kroenke, Spitzer & Williams, 2002).
WSAS	Work and Social Adjustment scale (Mundt, Marks, Greist & Shear, 2002).
EQ-5D-5L	Standardised Health Measure, visual analogue scale of overall health (Euroqol group, 1990)
CSRI	Client Services Receipt Inventory Interview (Beecham and Knapp, 2001)
SF-36	Short Form Health Survey (Ware et al 2000)

Statistical Methods

- ***Sample Size.*** Effect size same as CHAMP study, 90% power, 5% significance, 75% follow up, n=156.
- ***Randomisation.*** Nottingham Clinical Trials Unit. 1:1, blocks of varying size, stratified by county (site). Assessor of outcome/statistician blinded.
- ***Analysis.*** Intention to treat. Multi-level modelling. Published protocol and analysis plan.

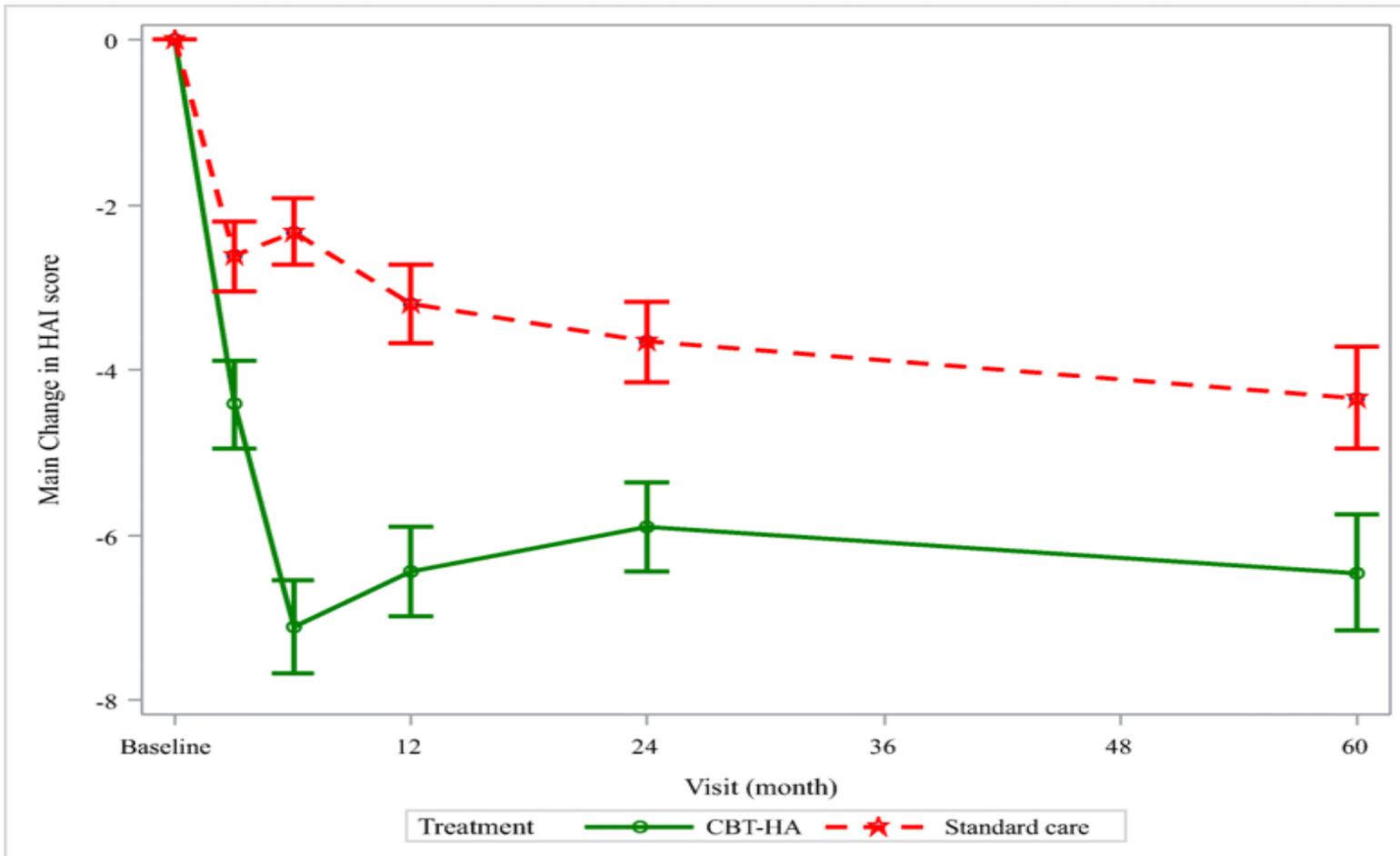
Health Economics

- Health and society perspective.
- NHS reference resource use at 2017 prices.
- EQ5D-5L to generate QALYs.
- Incremental Cost Effectiveness Ratio (ICER) = $(\text{Cost}_{\text{CBT}} - \text{Cost}_{\text{TAU}}) / (\text{QALY}_{\text{CBT}} - \text{QALY}_{\text{TAU}})$
- Net monetary benefit (NMB) was calculated as: $(\text{incremental benefit} * \text{willingness-to-pay (WTP) threshold}) - \text{incremental cost}$.

CHAMP RCT: face to face CBT (n=219) versus standard care (n=225).

Tyrer P et al HTA Report

2017



Remote CBT

- 4 experienced CBT therapists supervised by lead therapist from CHAMP study (HT).
- 6-12 CBT sessions, including one digital set up plus 3 booster sessions with text reminders of appointments/ relapse plans.
- CBT as CHAMP delivered by Webex and/or phone
- Tackle beliefs about health, illness, sources of distress. Behavioural strategies to test beliefs and alternative coping. Relapse plans.

Quick Start

Meeting Info

Anxiety Equa...^x

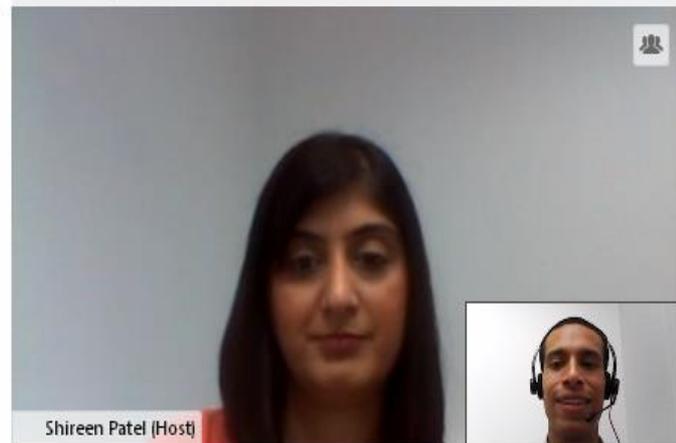
+ New Whiteboard



04

Anxiety = $\frac{\text{Likelihood of event}}{\text{Ability to cope}} \times \text{Awfulness and cost} + \text{Support factors}$

Participants



- Sam Malins (me)
- Shireen Patel (Host)

Audio

Chat

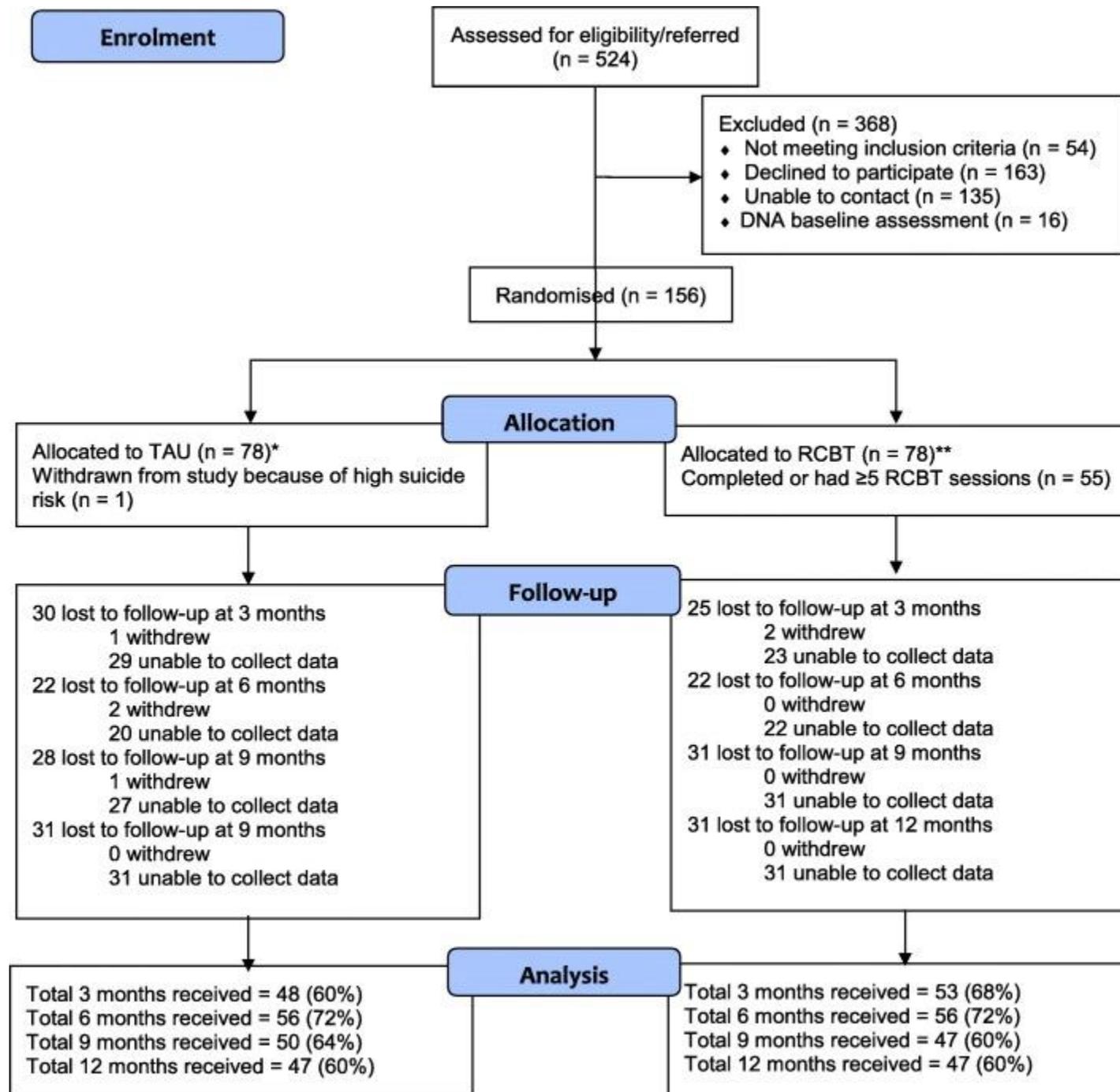
Recording...

Connected



Results

- 470 eligible patients referred – 156 (33%) randomised.
- No adverse events.
- 71% completion of minimum of 6 remote CBT – 75% videocall, 25% phone call.
- Familiarity with internet associated with videocall.
- 20 unblindings – 19 in CBT, 1 in TAU, outcome assessed by another RA subsequently in each instance.
- 72% follow up at 6 months in both groups, 60% in both groups at 12 months.



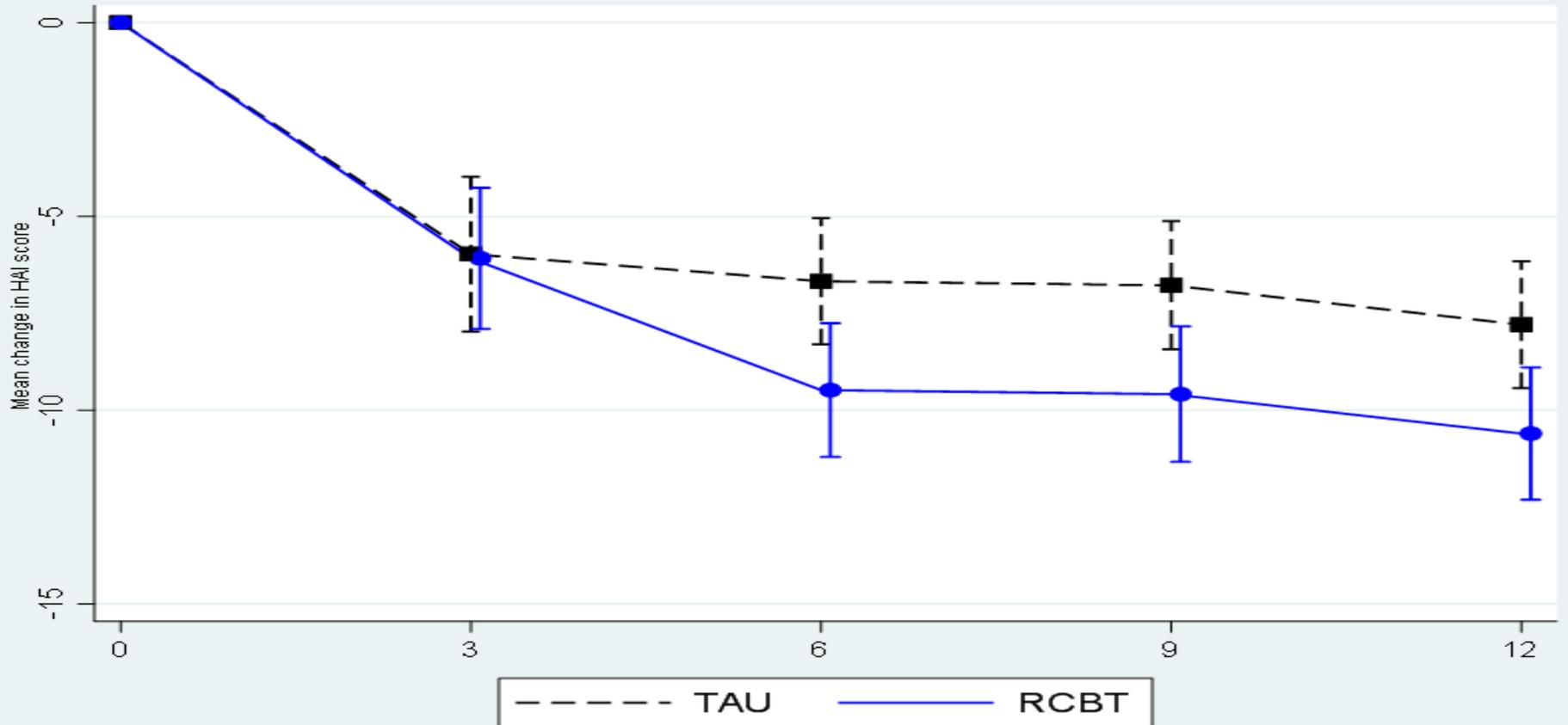
Baseline characteristics/referring source

	RCBT	TAU
	(n=78)	(n=78)
Age, median (range) years	31(18-79)	33 (19-83)
Female, n (%)	56 (72%)	52 (67%)
Employed, n (%)	32 (41%)	29 (37%)
First degree or higher, n (%)	24 (31%)	25(32%)
No qualifications, n (%)	7 (9%)	3 (4%)
Married/partner, n (%)	32 (41%)	39 (50%)
White British, n (%)	58 (74%)	58 (74%)
GP, n (%)	63 (81%)	62 (79%)
Medical Specialties, n (%)	9(12%)	7 (9%)
Emergency Dept., n (%)	4 (5%)	6 (8%)
Walk in Centre, n (%)	2 (3%)	3 (4%)

Baseline clinical characteristics

Baseline Scores	RCBT	TAU
SHAI, mean (sd)	27.3 (5.4)	26.4 (5.1)
GAD7, mean (sd)	12.9 (5.5)	12.7 (6.1)
PHQ9, mean (sd)	13.4 (6.5)	13.1 (6.7)
PHQ15, mean (sd)	14.2 (5.6)	13.9 (6.5)
EQ5D-5L Utility Value	0.61 (0.28)	0.60 (0.29)
(VAS), mean (sd)	54.8 (21.7)	57.0 (22.6)
WSAS, mean (sd)	19.3(11.4)	20.4 (10.5)
Unscheduled care attendances, last 12 months, median (range)	6.5 (2-125)	5.0 (2-34)

Primary outcome- SHAI



Significant improvements in health anxiety (-2.81, 95% CI -5.11, -0.50, $p=0.017$) at 6 months, also 9 and 12 months.

Effectiveness

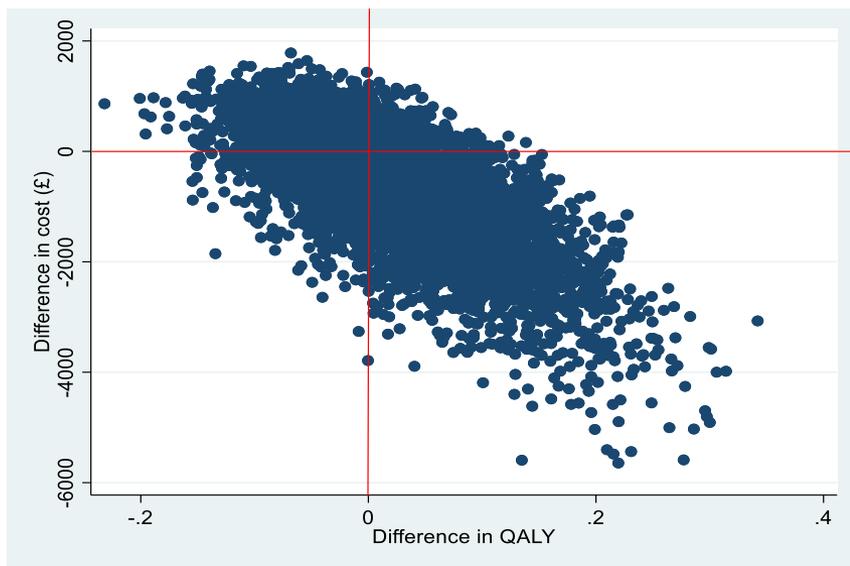
	CBT Mean change (95% CI)	TAU Mean change (95% CI)	Difference (95% CI)	P value
SHAI				
3 m	6.1(7.9,4.3)	6.0(8.0,4.0)	0.1(2.8,2.6)	0.936
6 m	9.5(11.2,7.8)	6.7(8.3,5.0)	2.8(5.1,0.5)	0.017
9 m	9.6(11.3,7.8)	6.8(8.4,5.1)	2.8(5.1,0.5)	0.017
12 m	10.6(12.3,8.9)	7.8(9.4,6.2)	2.8(5.1,0.5)	0.017
GAD-7				
3 m	3.7(5.1, 2.3)	4.8(6.2,3.4)	-1.1(0.8,3.1)	0.265
6 m	6.2(7.6, 4.8)	3.8(5.2,2.4)	2.4(4.4, 0.4)	0.020
9 m	5.4(7.1, 3.7)	4.5(6.0,3.0)	0.9(3.0, -1.2)	0.408
12 m	6.7(8.1, 5.2)	3.9(5.4,2.5)	2.8(4.8, 0.7)	0.009

	CBT	TAU	mean diff	p
PHQ-9				
3 m	3.2(4.7, 1.8)	3.0(4.4, 1.6)	0.2(2.2, -1.7)	0.812
6 m	4.7(6.0, 3.3)	3.1(4.5, 1.8)	1.6(3.5, -0.3)	0.105
9 m	4.4(6.1, 2.8)	3.2(4.8, 1.7)	1.2(3.2, -0.8)	0.250
12 m	5.1(6.4, 3.7)	2.7(4.1, 1.3)	2.4(4.2, 0.5)	0.013
PHQ-15				
3 m	0.4(1.6, 0.9)	1.7(3.2, 0.2)	1.3(-0.5, 3.2)	0.157
6 m	3.0(4.1, 1.8)	1.6(2.9, 0.3)	1.3 (3.1, -0.4)	0.137
9 m	2.6(4.2, 1.0)	2.2(3.5, 0.9)	0.4(2.4, -1.5)	0.669
12 m	3.3(4.6, 2.0)	1.8(3.0, 0.6)	1.6(3.4, -0.2)	0.089
EQ5D(VAS)				
3 m	8.7(3.7, 13.8)	2.8(2.4, 8.0)	5.9(-1.2,13.1)	0.103
6 m	13.7(9.0 18.3)	11.1(6.3,15.9)	2.6(-4.0, 9.1)	0.446
9 m	10.2(5.3 15.2)	2.9(2.1, 7.9)	7.3(-0.02,14.7)	0.051
12 m	13.8(8.9 18.7)	4.3 (-0.9, 9.4)	9.6(2.7, 16.4)	0.006
WSAS				
3 m	4.5(6.6, 2.3)	3.4(5.6, 1.1)	1.1(4.1, -1.9)	0.468
6 m	7.5(9.9, 5.2)	4.9(7.0, 2.8)	2.6(5.7, -0.5)	0.094
9 m	7.3(9.8, 4.8)	5.8(8.2, 3.4)	1.5(5.0, -1.9)	0.377
12 m	7.9(10.2, 5.6)	5.4(7.8, 3.0)	2.5(5.7, -0.8)	0.131

Economic results

	RCBT		TAU		Unadjusted difference in change		
	n	Mean (s.d) £	n	Mean (s.d.) £	Mean (95% CI) £ (p-value)		
CBT sessions	78	496 (294)	78	0 (0)	496 (431 to 562) (0.000)		
Technology	78	35.8 (0)	78	0 (0)	35.8 (35.8 to 35.8) (N/A.)		
Outpatient hospital visits	35	608 (871)	34	728 (706)	-120 (-502 to 261) (0.531)		
Inpatient hospital visits	38	22 (87)	37	258 (656)	-236 (-450 to -23) (0.031)		
Primary and community care	38	798 (838)	35	2066 (5224)	-1268 (-2981 to 444) (0.144)		
Travel	33	36 (46)	35	50 (109)	-14 (-55 to 27) (0.495)		
Medication	37	219 (402)	34	436 (1082)	-217 (-597 to 163) (0.259)		
Informal care	36	162 (536)	34	293 (1253)	-130 (-586 to 325) (0.569)		
Total cost	29	2197 (1048)	26	3261 (5010)	-1064 (-2973 to 845)		
Net monetary benefit (NMB)							
WTP threshold	£5,000	£10,000	£15,000	£20,000	£25,000	£30,000	£35,000
Observed values	£1,414	£1,764	£2,114	£2,464	£2,814	£3,164	£3,514

Cost effectiveness plane



Conclusions

- Doctors recognise people with health anxiety accurately (90.1%); 33% take up versus <10% in other studies.
- A non-stigmatising explanation (“help to cope with your distress about bodily symptoms” did not upset anyone) and CBT delivered remotely engaged people in the trial and therapy.
- Limitations: low completion of health economics interviews, sample biased to younger age (median 32 yrs, range 18-79).
- Clinically effective for at least 12 months. Reduces worry to manageable levels.
- Reduces costs by £1,000 per patient over 12 months (hospital and community).
- Ready for implementation.