The IPCRESS Trial

Delivering CBT over the Internet

2005-2008

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Researchers

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Depression in Primary Care

- 1 in 6 people present with depression at some point in their lives: most in primary care
- The number of patients treated for depression in primary care is increasing
- The number of prescriptions and their cost is increasing

Background

- Public attitudes to psychotherapy are relatively favourable compared to attitudes to antidepressants(1)
- Cognitive Behavioural Therapy (CBT) is an effective treatment for depression and can improve long-term outcome (2)

- (1) Tylee 2001
- (2)Churchill et al 2001

Background

- People use computers for all sorts of live interactions
- CBT-based computerised interventions have been tested in primary care and found to be effective (3)
- (3) Proudfoot et al 2004

Computerised CBT packages

- Advantages
- Cheap
- Accessible
- Effective

- Disadvantages
- Inflexible
- Impersonal

IAPT

- UK Health secretary Alan Johnson: 'Improving Access to Psychological Therapies' (IAPT) is "the most important development we have undertaken in health care". UK Government's plans include training a new workforce of 3,600 therapists

Face to Face CBT

- Shortage of therapists: unacceptable waiting lists (4)
- Geographically inequitable availability of CBT therapists in the NHS (5)
- Demonstration sites in Newham and Doncaster

- (4) Clinical Standards Advisory Group 1999
- (5) Shapiro et al 2003

PsychologyOnLine

- A website providing a link to psychologists throughout the UK and elsewhere
- Running since 2001
- >500 clients treated
- Access for anyone with PC and Internet; broadband not required

Who might find this useful?

- Computer Literate
- Working people
- Those living in areas or countries poor in psychology services
- Disabled
- Social phobics
- Non-native speakers

Other potential gains

- Good for psychologists, especially those prepared to work anti-social hours
- Writing about distress can lead to improvements in health (6,7)

- (6)Pennebaker 1996
- (7)Smyth 1999

The trial 1

- *Design*: multi-centre 2 parallel group RCT with individual randomisation
- *Comparison group*: waiting list.
- *Recruitment* : newly diagnosed depressives in primary care
- 3 centres: Bristol, Warwick and London; 20+ practices in each

The trial 2

- Patients recruited by GPs in surgery or by computer search
- Screened using the Beck Depression Inventory (BDI)
- Further assessment included CIS-R and measures of quality of life (EQ-5D) and social function (SF-12)

Eligibility

- BDI of 14 or more
- Access to Internet
- ICD-10 diagnosis of depression
- 18-75
- Exclusion criteria: Alcohol dependency, severe mental illness, CBT within the last 2 years

The Intervention

- 10 hours of CBT over 16 weeks
- Model as described by Judith Beck (8)
- Selected sessions transcribed and rated by independent researchers to rate fidelity to the model

- (8) Cognitive Therapy, Basics and beyond 1995

Primary Outcome

RECOVERY

BDI score of <10 at 4 month follow up

Secondary outcomes

- Recovery at 8m
- BDI score at 4m and 8m as a continuous variable
- SF-12 mental sub-score at 4m and 8m
- EQ-5D AT 4m and 8m
- Treatment received (CACE)
- Therapist effects

Subgroup analyses

Interactions between randomisation group and:

- BDI Severity (Mild & moderate vs severe)
- Prescription of antidepressants

Results: recruitment

- 512 referred to IPCRESS.
- 393 eligible for randomisation.
- Of these, 95 declined to participate and 1 was excluded in error.
- The proportion of eligible patients randomised: 297/393 (75.6%)
- The proportion randomised by centre:
- Bristol: 240/294 (81.6%)
- London: 41/78 (52.6%)
- Warwick: 16/21 (76.2%)

Generalisability

Randomised n=297

female 202 (68.0%)

Practice counsellor 170 (57.2%)

Mean age 34.9 (SD: 11.6)

Deprivation (IMD score) 21.9(SD:15.6)

Randomised+ Declined (n= 393)

female 262 (66.8%)

Practice counsellor 237 (60.3%)

Mean age 35.0 (SD 11.8)

Deprivation (IMD score) 22.7(SD:15.33)

Baseline comparability 1

Intervention n=149	**Waiting list n= 148**
Female 103 (68.9%)	Female 99 (66.9%)
Age 35.6 (SD 11.9)	Age 34.3 (SD 11.3)
Preference for CBT	Preference for CBT
122 (81.9%)	134 (90.5%)
BDI 32.8 (SD8.3)	BDI 33.5 (SD 9.3)
Severe (>28) 103 (67.8%)	Severe (>28) 103 (69.6%)

Baseline comparability 2

Intervention

Employed 65.1%

Home owner 46.3%

A level + 65%

Treated past depression 56.4%

3 or more recent LEs 12%

Waiting list

Employed 62.8%

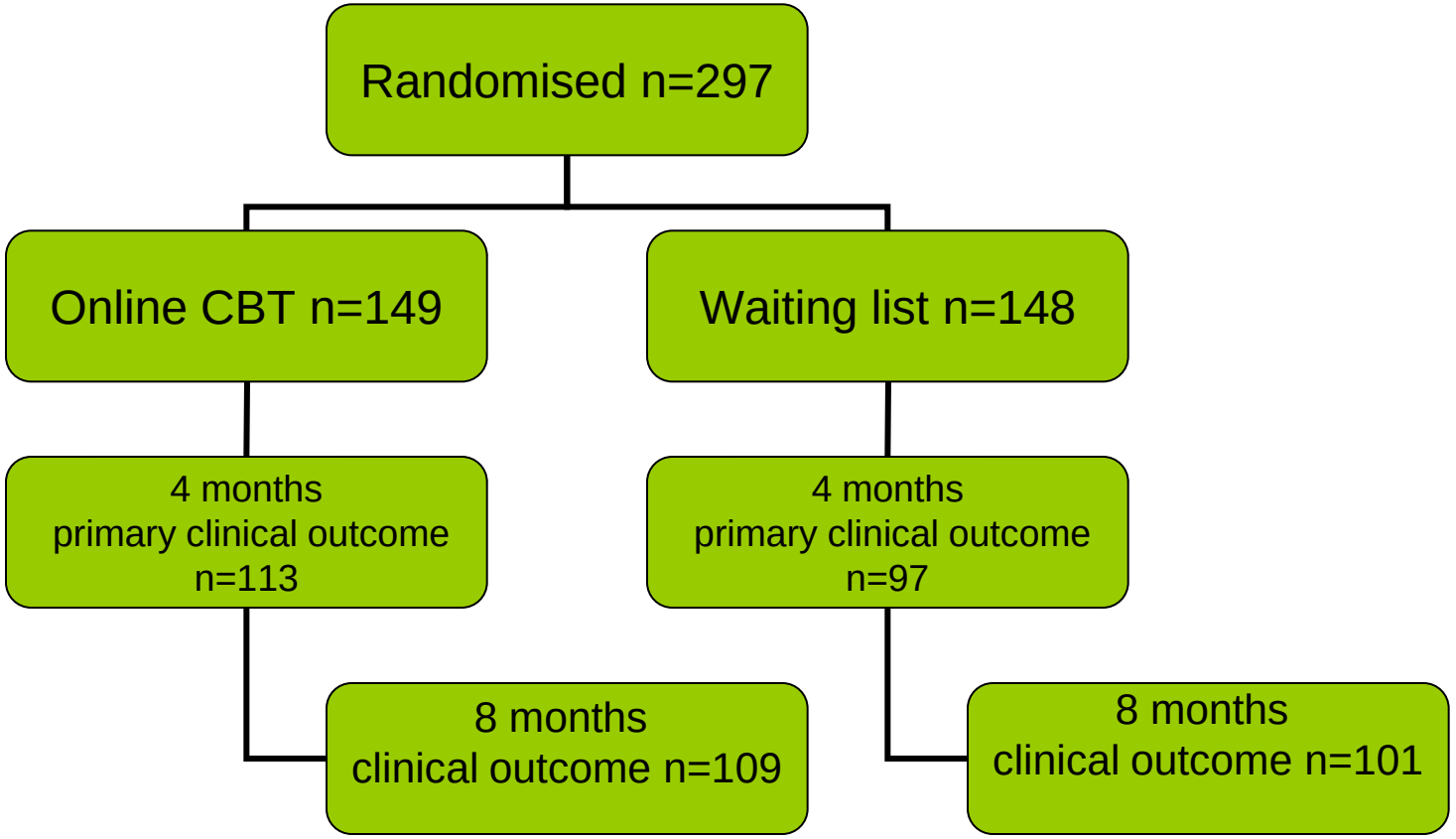
Home owner 34.5%

A level + 62.8%

Treated past depression 53.4%

3 or more recent LEs 21%

Participant flow through the trial



Primary outcome: recovery (BDI<10) at 4m adjusted for baseline BDI score

Online CBT		Waiting List		OR (95% CI)	p value
n	recovered (%)	n	recovered (%)		
113	43 (38)	97	23 (24)	2.39 (1.2, 4.7)	< 0.011

Adjusted primary outcome

Adjusting the primary outcome for

- Baseline imbalances
- Clustering by practice
- Time to follow-up
- Antidepressant use at 4m

Had little effect on the outcome

NNT = 7 (95%CI 4,50)

BDI as a continuous outcome at 4 months

Online CBT		Waiting List		Adjusted difference in means (95% CI)	p value
n	Mean (SD)	n	Mean (SD)		
113	14.5 (11.2)	97	22.0 (13.5)	-7.1 (-10.0, -4.2)	<0.001

Recovery at 8 months (BDI<10)

Online CBT		Waiting List		OR (95% CI)	p value
n	recovered (%)	n	recovered (%)		
109	46 (42)	101	26 (26)	2.07 (1.1,3.9)	< 0.02

BDI as a continuous outcome at 8 months

Online CBT		Waiting List		Adjusted difference in means (95% CI)	p value
n	Mean (SD)	n	Mean (SD)		
109	14.7(11.6)	101	22.2(15.2)	-6.2 (-9.3, -3.9)	<0.001

Repeated measures analysis

Average intervention effect across 4m and 8m follow-up:

OR = 2.12 (95%CI 1.26, 3.55)

Other secondary outcomes

- Difference between the 2 groups in SF-12 scores and EQ5D scores at 4m
- This was maintained at 8m in the EQ5D; (possible difference in the SF-12 at 8m)
- No difference in antidepressant use between the 2 groups at 4 and 8m

Subgroup analyses 1

- At 4m, effect greater in those with more severe depression at baseline (interaction p-values 0.025 and 0.021 for binary and continuous BDI)
- At 8m this was maintained for the continuous outcome (p=0.040) but not for the binary variable

Subgroup analyses 2

- At both follow up points the improvement in BDI score for those with baseline >28 was ~10 compared to 6-7 overall
- For the binary outcome at 4m the intervention effect was only observed in those with a baseline BDI >28

Subgroup analysis 3

- At neither 4 nor 8 months was there any evidence of differential effects of the intervention according to whether or not the participant was being prescribed antidepressants at baseline

Treatment actually received

- Crude estimate of difference in BDI between those who received at least 5 sessions of CBT and the rest:

  -6.2 (-9.3, -3.1)
- CACE (complier average causal effect) estimate of difference between the intervention and waiting list groups:

  -10.0 (-14.2, -5.7)

Therapist effects

ICCs:

- for 113 allocated to intervention =0.015
- For 81 who received at least 5 sessions of online CBT = 0.061
- Comparison with waiting list using fully heteroscedastic model led to an estimated OR of 2.41 (1.19,4.87)

Comparison with other CBT studies in UK primary care

Study	Timepoint (m)	Effect size*
IPCRESS 1	4	0.81
IPCRESS 2	8	0.70
Ward 1	4	0.52
Ward 2	12	0.10
Proudfoot 1	3	0.51
Proudfoot 2	6	0.62
*using SD of baseline BDI in all cases		

Integrity of CBT

- 40 randomly selected transcripts independently rated by two psychologists
- Mean CTS-R scores of 31 and 32
- Compare: often-used cut-off of 39

Economic evaluation

- Perspectives:
  - health care provider (UK NHS)
  - patients
  - society
- Timescale: eight months from randomisation to final follow up

NHS resources

- Primary and community care – all cause
  - GP and nurse consultations
  - Other professionals e.g. counsellor, occupational health
  - Walk-in centres, NHS Direct
- Prescribed medication – all cause
- Depression-related secondary care
  - Outpatient visits, A&E, Inpatient stays

Patient-related costs

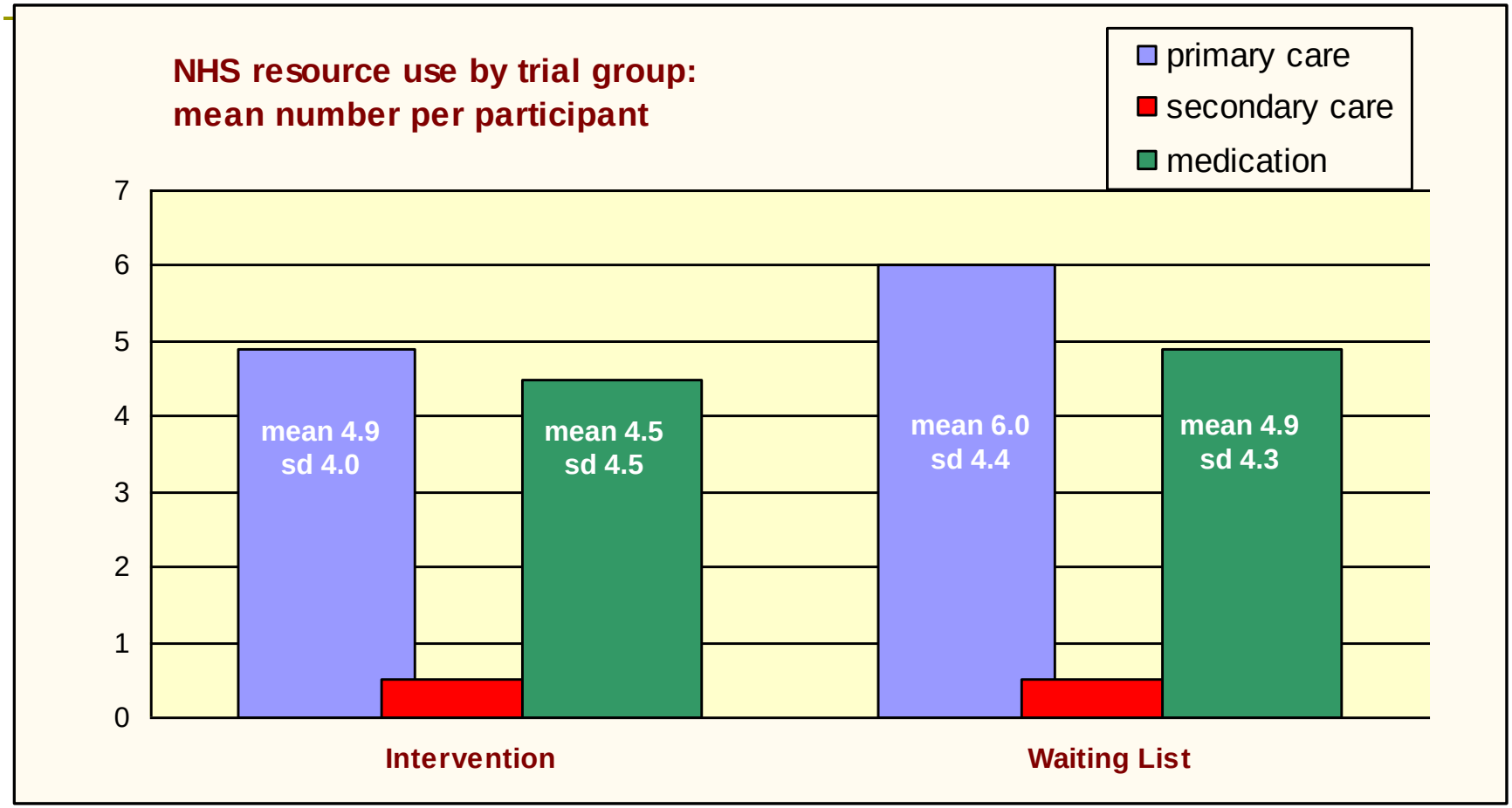
- Private health care
- Travel
- Over the counter medication
- Time off work and loss of earnings
- Extra social or domestic help

Collecting resource use data

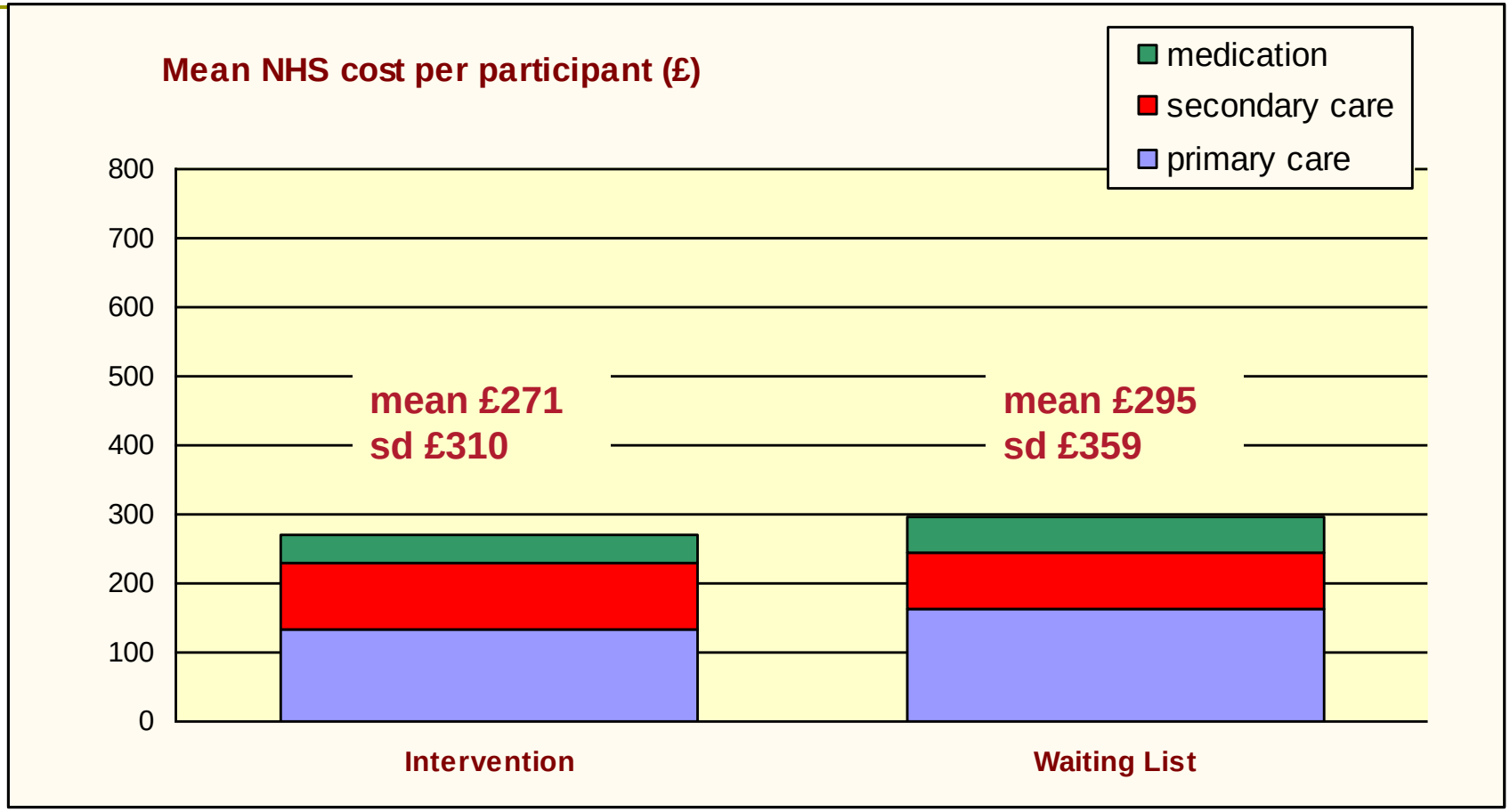
- Patient diary: 4-monthly intervals
  - NHS resources
  - personal expenditure
  - monthly email reminder

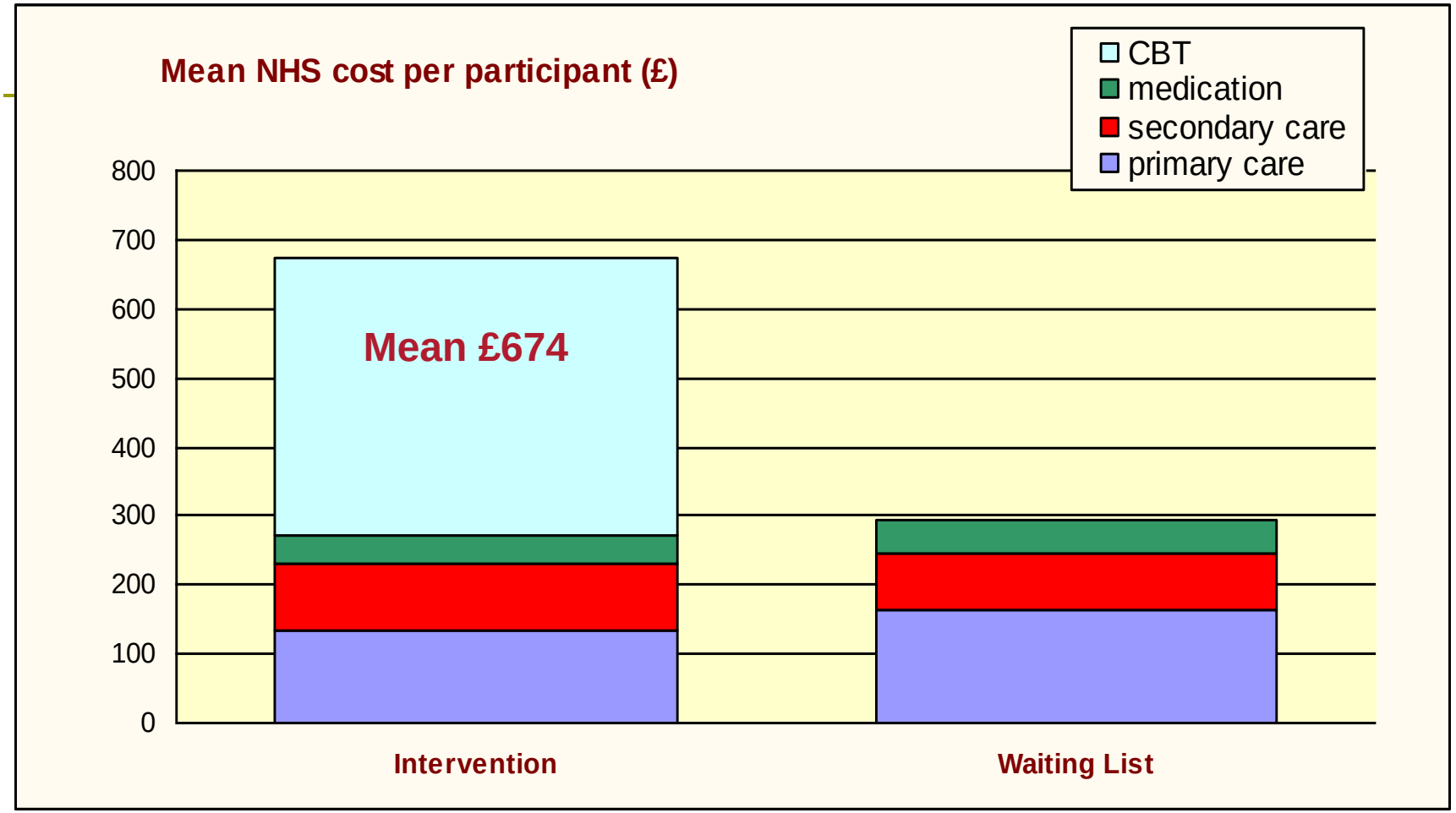
- Trial data: number of online CBT sessions

Results: NHS resource use



Results: NHS costs

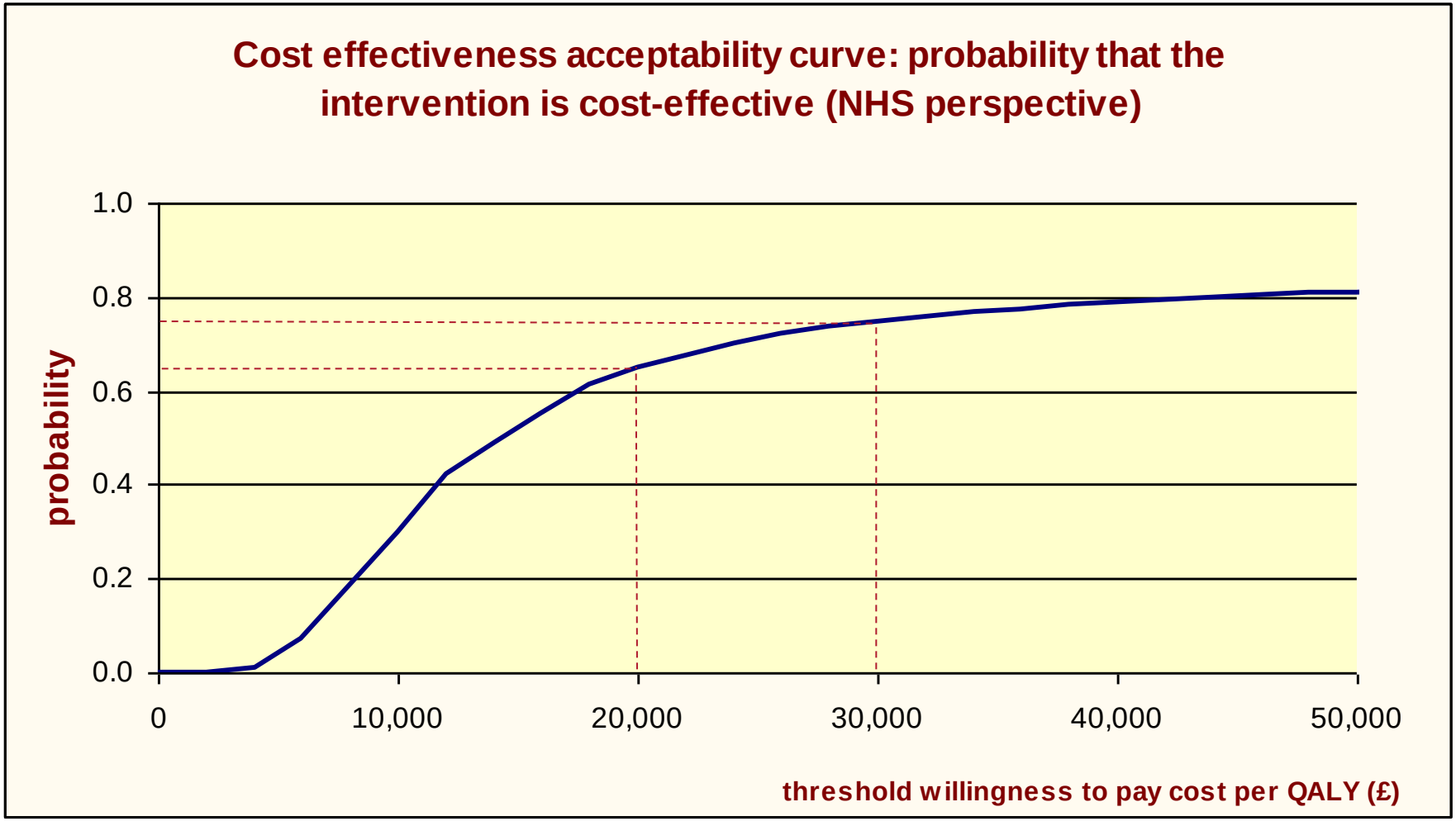




Incremental cost per patient: **£378**

Cost-effectiveness (NHS perspective)

- **BDI**
  - Recovery 42% vs 26% → Cost per extra patient recovering: £2,370
  - 14.2 vs 22.2 → Cost per point improvement in BDI: £60
- **QALYs**
  - Intervention: 0.522 (0.104)
  - Waiting list: 0.495 (0.124) →
  - Incremental gain: 0.027
  - Cost per QALY: £13,700
    (95% CI: -0.012 to 0.066)


Cost effectiveness acceptability curve: probability that the intervention is cost-effective (NHS perspective)
probability
1.0
0.8
0.6
0.4
0.2
0.0
0
10,000
20,000
30,000
40,000
50,000
threshold willingness to pay cost per QALY (£)

Private treatments

(counselling, complementary therapies etc)

	Intervention	Waiting list
n	72	63
number (%) using private treatment	18 (25%)	19 (30%)
mean (sd) cost	£207 (£189)	£263 (£327)
median (IQR)	£170 (£50 to 350)	£148 (£110 to £300)
mean (sd) overall cost per patient	£52 (£129)	£80 (£214)
Incremental cost	£-28 (£-87 to £32)	

Time off work

	Intervention	Waiting list
n	73	64
number reporting some time off	21 (29%)	23 (36%)
mean (sd) number of days off	27 (25)	49 (57)
median (IQR)	21 (10 to 41)	29 (6.5 to 67)
mean (sd) number of days off overall	7.7 (18)	17.6 (41)
range	0 to 103	0 to 178
mean (sd) cost per participant	£399 (£939)	£910 (£2135)
Incremental cost	**£-512** (£-1057 to 34)	

Comparison with the literature

- NICE commissioned report by NCCMH, 2004
  - Economic model: AD plus CBT vs AD
  - £14,540 per QALY

- Computerised CBT *Beating the Blues (*McCrone et al *Br J Psych 2004)*
  - *80% cost-effective at £40 per point improvement on BDI*
  - *99% cost-effective at £15,000 per QALY*

Qualitative study
Health Expectations; in press

Online CBT is acceptable and helpful to those who

- are comfortable with computers
- Like writing their thoughts and feelings down, and the opportunity to reflect and review
- Are attracted to the 'anonymity' of an online relationship

Positive views of the 'impersonal nature of the medium'

- 'I don't think I could have sat down with someone and talked face to face…because I wouldn't have been as honest
- ' I didn't feel it was anonymity come the end..I didn't feel like I was typing things on a computer'
- 'I warmed to him straightaway, you can do that over the Internet

Less positive views

- ‘are they concentrating on what you’re saying? Or are they doing something else..having a cigarette?
- ‘I don’t think he could make a full assessment of my condition because I don’t believe I could explain my condition simply in words

What does it all mean?

- CBT is effective when delivered online
- It is effective in those with severe symptoms
- The effect size is substantial for such a brief intervention
- It is cost-effective
- CBT delivered online is acceptable to some patients

More questions

- If its not CBT, does it matter?
- Is there added value in doing therapy online for some people?
- Someday, will all therapy be like this?
- Skype?

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