

Comparing characteristics and outcomes of individuals who participated in a trial versus those that did not

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BACKGROUND

- Participants in trials may differ from non-participants
- This may bias the estimate of treatment effects

AIM

To compare participants in a randomised controlled trial (RCT) with non-participants at screening and at outcome

METHODS

- RCT of telephone-delivered cognitive behavioural therapy (tCBT) for preventing chronic widespread pain in those at high-risk

- Screening questionnaires sent to GP patients in Scotland
- Eligibility Criteria: Pain + at least 2 of 3 risk factors (illness behaviour, somatic symptoms, sleep problems)
- 4,435 high-risk individuals eligible for trial identified; 996 of these recruited to the trial
- Participants allocated tCBT or usual care (UC)
- tCBT Intervention: Assessment, six weekly-sessions, 3 & 6 month boosters
- Followed up at 12 months

RESULTS

Non-participants differed from participants at screening

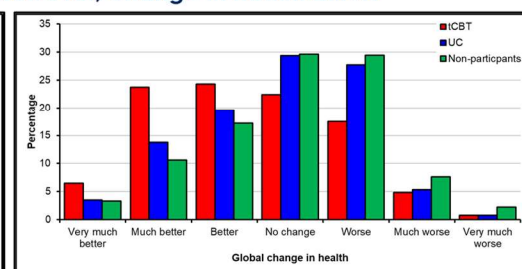
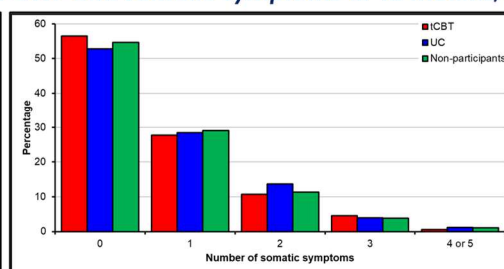
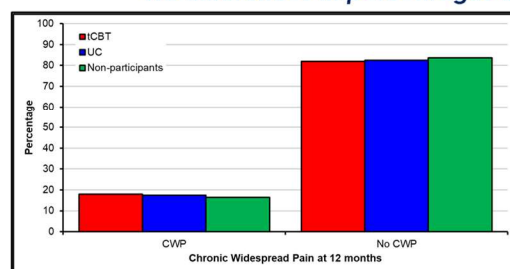
	Participants n=996	Non-participants n=3,439
Age (median)	59.1 years	54.8 years
Difference (95% CI)	4.2 (2.7-5.6)	
% Female	41.5%	35.8%
Difference (95% CI)	5.7% (2.2-9.2%)	
Risk Factors		
Illness behaviour	9.83	8.34
Difference (95% CI)	1.49 (1.26-1.72)	
Somatic symptoms (2-5)	19.4%	16.1%
Difference (95% CI)	3.2% (0.5-6.0%)	
Sleep Problems	10.18	9.70
Difference (95% CI)	0.48 (0.15-0.81)	

No differences in illness behaviour at 12 months; sleep improved in tCBT group only

	tCBT n=384	UC n=441	Non-participants n=827
Illness behaviour			
Mean score	8.21	8.96	8.16
Mean diff. (UC vs NP) ¹	0.34 (-0.18 – 0.87)		
Mean diff. (tCBT vs NP) ¹	-0.47 (-1.21 – 0.26)		
Sleep problems			
Mean score	8.20	9.20	9.31
Mean diff. (UC vs NP) ¹	-0.17 (-0.75 – 0.41)		
Mean diff. (tCBT vs NP) ¹	-1.13 (-1.83 – -0.42)		

¹Adjusted for age, gender, number of risk factors at baseline, and outcome at baseline

No differences in percentages of CWP and somatic symptoms at 12 months; however, change in health differs



DISCUSSION

- Limited to individuals consenting to future study contact
- Low response rates at follow-up, particularly in non-participants
- tCBT improves sleep and global health in high-risk individuals
- Findings support use of tCBT in at-risk populations

CONCLUSIONS

- Participants differed from non-participants in age & pain risk factors
- Using non-participant comparison group confirms tCBT as effective for some pain risk factors

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- Poster produced with help of Open AI's large language model Chat-GPT-4