

Cognitive behavioral therapy and physical exercise for climacteric symptoms in breast cancer patients experiencing treatment-induced menopause

A randomized controlled multicenter trial

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Breast cancer and premature menopause

- 12.000 new cases each year in the Netherlands; 30% premenopausal
- Ovarian damage due to treatment
- Early onset of menopause
- Primary symptoms menopause: hot flushes, night sweats, vaginal dryness, urinary incontinence
- Secondary symptoms include insomnia, weight gain, psychological distress, and reduced HRQL
- Hot flushes most disruptive
- Dysfunction of thermoregulatory center in hypothalamus, due to changes in estrogen level
- Other causes

Medical treatments for menopausal symptoms

- Hormone replacement therapy (HRT)
- Non-hormonal treatment, for example:
 - Clonidine (anti-hypertensive agent)
30-50% decrease of hot flush/ night sweat
 - SSRI (anti-depressant agent)
effective but adverse effects limit use



No demonstrated efficacy in acute menopause

Behavioral interventions for menopausal symptoms

- Cognitive behavioral therapy (CBT)
 - Information about symptoms
 - Monitoring and modifying symptoms
 - Stress management and relaxation
 - Cognitive restructuring of automatic thoughts
 - Encouraging helpful behavioral strategies
- Physical exercise (PE)
 - 2,5-3 hours per week/ 12 weeks
 - 60-80% maximum heart rate
 - Affect thermoregulatory system

Study objectives

To evaluate, in the context of a RCT, the efficacy of an intervention program (CBT, PE, combination CBT/PE, control) in reducing menopausal symptoms in women with primary breast cancer who undergo premature treatment-induced menopause.

Secondary outcomes will include sexual functioning, urinary symptoms, body- and self image, psychological distress and HRQL.

Study sample

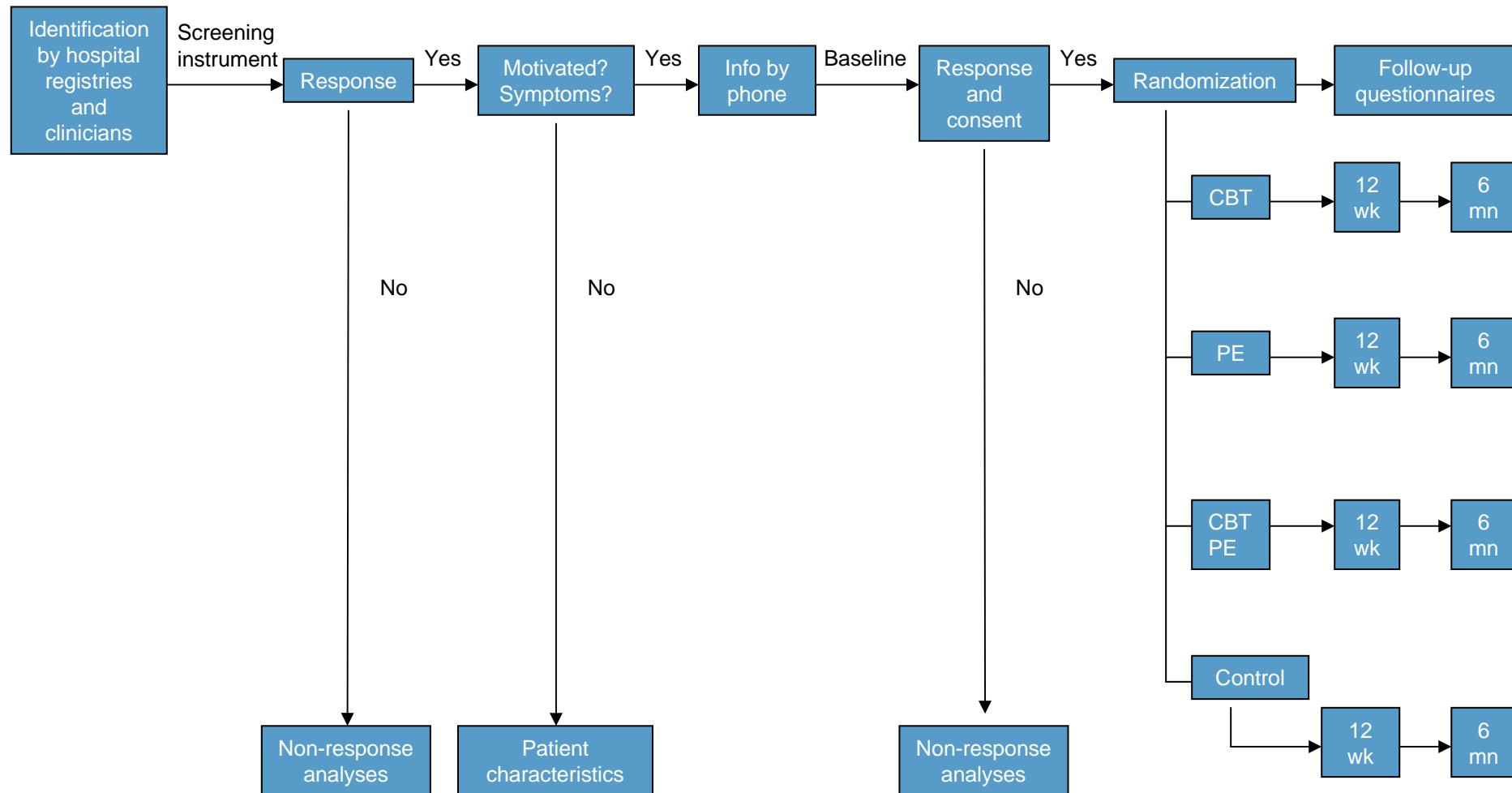
Inclusion

- Minimum of 325 women; < 50 years of age; primary breast cancer
- Premenopausal at time of diagnosis
- Completed adjuvant chemotherapy; hormonal therapy
- Disease-free at time of study entry
- Presence of hot flushes, night sweats, vaginal dryness
- 5 years retrospective, 2 years prospective recruitment

Exclusion

- Lack basic proficiency in Dutch
- Serious cognitive/ psychiatric problems; serious physical comorbidity
- BMI \geq 30
- Concurrent studies

Study design



Outcome measures

- Menopausal symptoms (FACT-ES)
- Vasomotor symptoms (Hot Flush Rating Scale)
- Urinary symptoms (BFLUTS)
- Sexuality (SAQ)
- Body image & self-image (QLQ-BR23)
- Psychological distress (HADS)
- Generic health-related quality of life (SF-36)



Cognitive behavioural therapy

- 6 weekly group sessions
- 1.5 hour per session
- 6-8 participants per group
- Homework assignments (15 minutes per day)
- Social workers/ psychologists



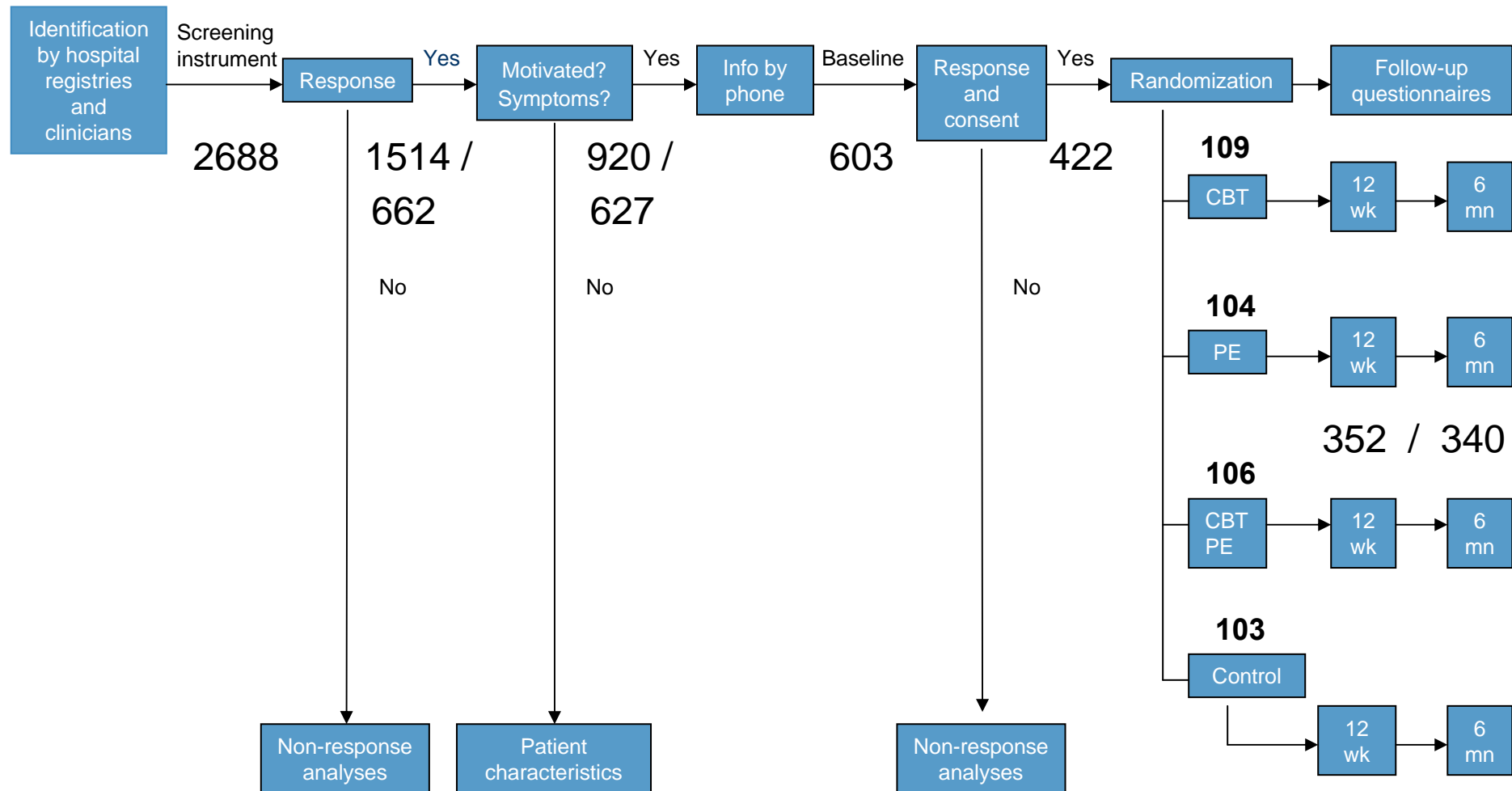
Primary focus CBT on hot flushes, night sweats and relaxation

Physical exercise

- 4 individual contacts with physiotherapist
 - Intake
 - Telephone contact (2x)
 - Evaluation
- Individually tailored
- 2.5-3 hours per week
- 12 weeks



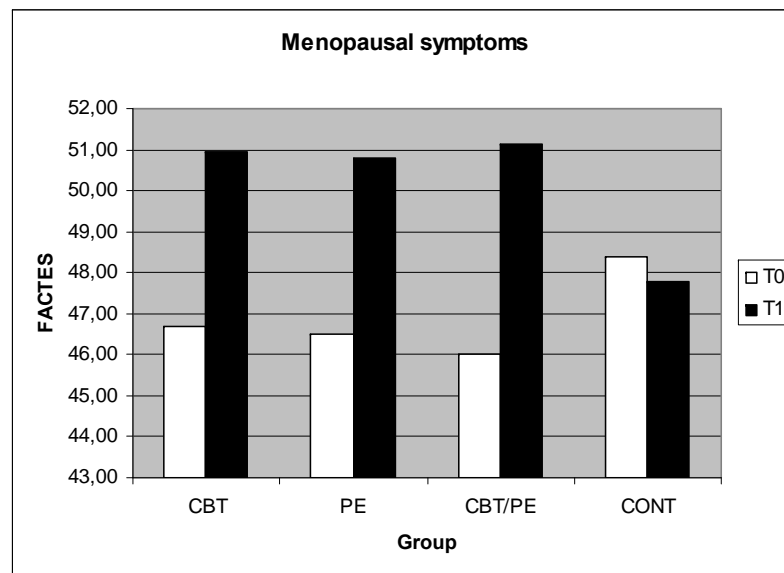
Flow of patients



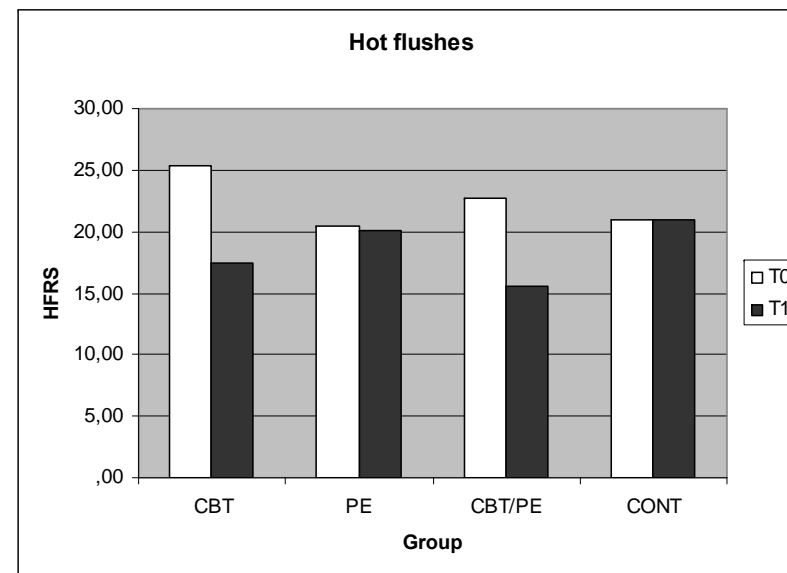
Patient characteristics

Characteristics	CBT N=86	PE N=87	CBT/PE N=90	Control N=89	p-value
Age; mean (SD)	48.7 (5.7)	48.3 (5.5)	49.0 (5.0)	47.7 (6.1)	0.468
Marital status					0.881
- Single	17	16	21	18	
- Married	69	70	69	71	
Education					0.280
- Low	12	6	6	5	
- Medium	40	38	48	49	
- High	32	41	36	34	
Work					0.871
- Fulltime	17	21	21	17	
- Parttime	45	47	48	54	
- Other	23	18	20	18	
Weight; mean (SD)	74.2 (10.4)	71.9 (12.6)	73.0 (11.3)	71.4 (11.2)	0.392
Health problems					0.784
- Yes	32	30	37	31	
- No	54	57	53	58	

Short term results

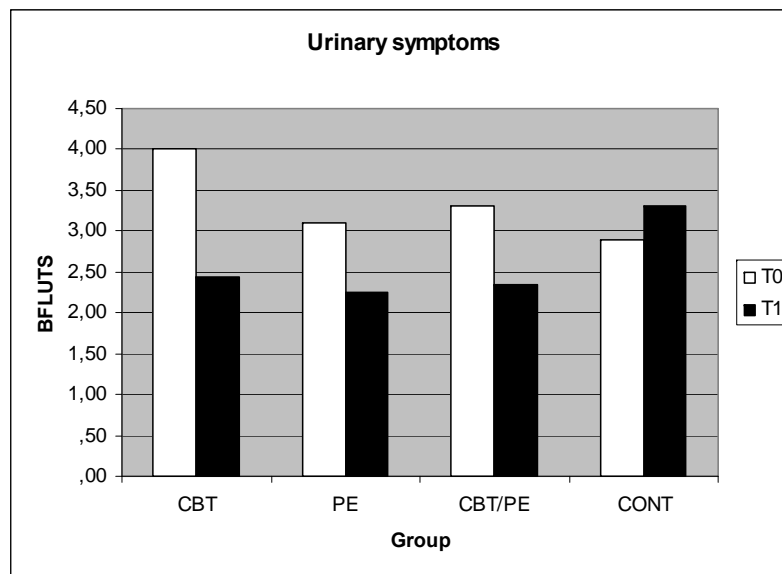


$p = 0.015$

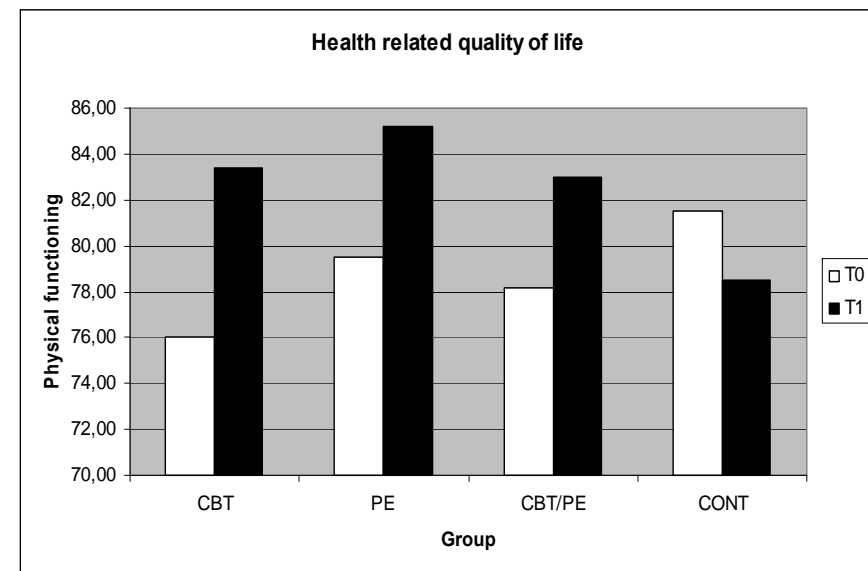


$p < 0.001$

Short term results

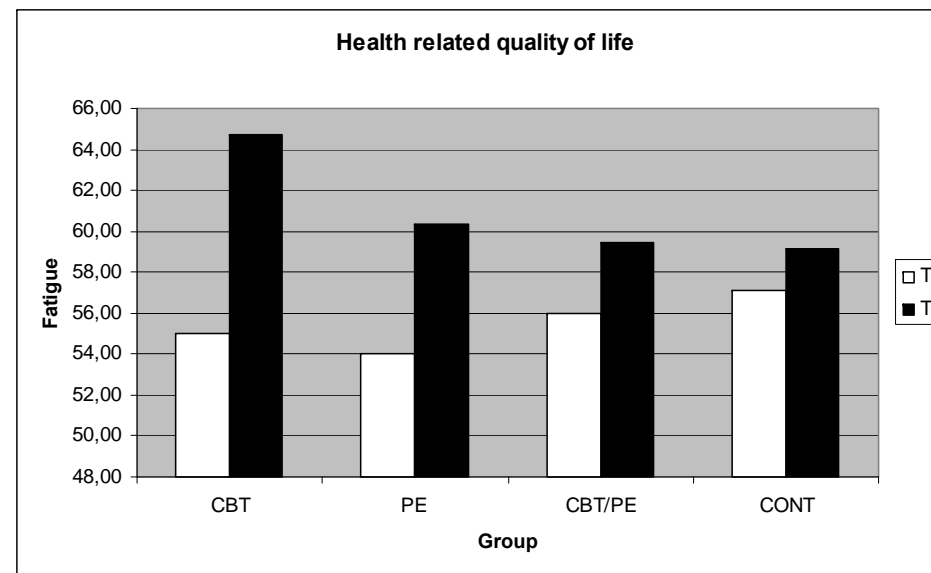


$p < 0.001$



$p = 0.004$

Short term results



$p = 0.033$

Conclusion

- Cognitive behavioral therapy and physical exercise appear to reduce menopausal and urinary symptoms
- Also, these interventions affect health related quality of life of breast cancer patients who experience treatment induced menopause
- However, non compliance rate is high. Reasons for non compliance are currently being explored

If proven to be effective over the longer follow-up period, implementation of these interventions, perhaps with modifications to increase compliance, will be a welcome addition to the regular medical care of breast cancer patients

Thank you

Contact information

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