

Table 1: Controlled clinical trials of biofeedback for cancer

Source: Lorenc A, CAM-Cancer Collaboration. [Biofeedback](#) [online document]. November 2024.

First author, year	Study design	Participants (number, diagnosis)	Interventions (experimental treatments, control)	Main outcome measures	Main results	Comments
Burish 1992	RCT	Cancer patients with history of pre-treatment anxiety and nausea or likely to have nausea (n=81)	1) Electromyography (EMG) biofeedback + relaxation training (RT) 2) Skin-temperature (ST) biofeedback + RT 3) RT only 4) Electromyography (EMG) biofeedback 5) Skin-temperature (ST) biofeedback 6) Nothing (told to relax) All sessions were 45mins before chemotherapy. Four training sessions and one follow up	1) Systolic blood pressure, diastolic blood pressure, pulse rate 2) Anxiety, depression and hostility (Multiple Affect Adjective Check List) 3) Anxiety and nausea as reported by the nurse	All RT groups (groups 1-3) had decreased nausea ($p<0.05$) and anxiety ($p<0.05$) and physiological arousal after chemotherapy compared with the groups receiving no RT (groups 4-6). EMG and ST biofeedback alone both reduced some indices of physiological arousal but did not reduce other measures of aversiveness of chemotherapy. No safety data reported.	Well performed. Unclear if sample was powered, and dividing into 6 groups means small group sizes. Stratified random assignment based on site of cancer, chemotherapy emetogenicity and antiemetic medication.

Cho 2021	RCT	Rectal cancer patients with sphincter-saving surgery (n=56)	<p>1) Biofeedback therapy after surgery, during the temporary stoma period. 1 or 2 times/week.</p> <p>2) Recommendation to do conservative self-rehabilitation e.g. Kegel (also given to group 1)</p>	<p>1) Anorectal manometry;</p> <p>2) Transanal ultrasound</p> <p>3) Subjective anorectal function (Cleveland Clinic Incontinence Score)</p>	<p>Final outcomes (12 months)</p> <p>No difference in primary outcome of subjective anorectal function ($p = 1.000$). Liquid stool incontinence had better tendency in biofeedback group ($p = 0.06$). Time-dependent serial changes in maximal sensory threshold significantly different ($p = 0.048$). Change of mean resting pressure (MRP) tended to be more stable in the BFT group ($p = 0.074$).</p>	<p>Powered sample size, good randomisation. Good detail about follow up/drop outs.</p> <p>Little information on what the biofeedback intervention actually involved, who ran the intervention etc.</p>
Kye 2016					<p>Interim outcomes (6 months)</p> <p>Significant difference in the change of mean resting pressures between biofeedback and control group ($p=0.002$).</p> <p>No difference in any other measures of anorectal dysfunction.</p> <p>No safety data reported.</p>	

De Lira 2019	RCT	Men undergoing radical prostatectomy for prostate cancer (n=31)	<p>1) Pelvic floor muscle training (perioperative) (physical therapist- guided sessions, including exercises and electromyographic biofeedback)</p> <p>2) Usual care</p>	<p>1) Urinary incontinence (International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF))</p> <p>2) Erectile dysfunction (International Index of Erectile Function (IIEF-5))</p>	<p>No significant difference in incontinence (frequency, severity or impact on QoL) between groups 3 months after surgery.</p> <p>No safety data reported.</p>	Powered sample, well randomised, and no loss to follow up.
Fink 2023	RCT	Any cancer patients (n=56)	<p>1) Alpha and theta neurofeedback training</p> <p>2) Mindfulness based therapy</p> <p>Ten sessions over 5 weeks.</p>	<p>1) Cognitive impairment (PCI)</p> <p>2) Emotional distress (DT, PHQ-8, GAD-7)</p> <p>3) Fatigue (MFI-20)</p> <p>4) Rumination (RSQ)</p> <p>5) Quality of life (QoL, EORTC-30 QoL)</p> <p>6) Self-efficacy (GSE)</p>	<p>No changes in cognitive impairment were found in either group (P=.079).</p> <p>Affective symptoms of distress (P≤.01), depression (P≤.05) and generalized anxiety (P≤.05) decreased significantly over time and self-efficacy improved. No differences between neurofeedback and mindfulness were found.</p> <p>QoL improved in neurofeedback group compared to mindfulness (P=.038)</p> <p>No change in fatigue, rumination</p> <p>No safety data reported</p>	<p>No non-treatment control.</p> <p>Sample size does not appear to have been calculated a priori and may be underpowered.</p> <p>Some dropouts only in mindfulness group.</p>

Hasuo 2023	RCT	Patients with incurable cancer and sleep disturbance (n=50)	<p>1) Heart rate variability (HRV) biofeedback single session in hospital and home practice</p> <p>2) Heart rate variability (HRV) biofeedback single session in hospital</p>	<p>1) Sleep efficiency</p> <p>a) Self-rated (PSQI)</p> <p>b) Objective (actigraphy)</p> <p>2) Heart rate variability</p>	<p>Significant improvement in sleep efficiency in group 1 compared to group 2 for both PSQI (p=0.017) and actigraphy (p<0.001). Higher increase in HRV in group 1 compared to group 2 (pre: p=0.016 and during: p<0.001).</p> <p>No adverse events were observed.</p>	<p>Sample was powered.</p> <p>Missing some details of randomisation. No registration details.</p> <p>No non-treatment control.</p>
Liang 2016	Non-randomised retrospective cohort study	Patients with anterior resection syndrome after low anterior resection for rectal cancer (n=61)	<p>1) Balloon training biofeedback, including strength, coordination and sensory training.</p> <p>2) Control group (not randomised) were healthy volunteers, argon plasma coagulation patients and haemorrhage patients.</p>	<p>1) Anorectal manometry</p> <p>(Also measured number of bowel movements/day and fecal incontinence , but these were not measured for the control group</p>	<p>Significant improvements in biofeedback group compared to control in anorectal manometry data: maximum resting pressure, P < .001; maximum squeeze pressure, P =0.001; and rectal capacity, P = 0.015.</p> <p>The number of biofeedback therapy cycles, the use of laparoscopic surgery, and current nonsmoking status might predict for positive therapeutic effects.</p> <p>No safety data reported.</p>	<p>This was a cohort study rather than a trial but was well conducted as such.</p> <p>However, as a cohort study it cannot control for time, attention, therapist interaction, or other treatments.</p>

Liu 2019	RCT	Patients with middle and low rectal cancer (n=126)	<ol style="list-style-type: none"> 1) EMG biofeedback. 3 20min session /week for 4 weeks. 2) Pelvic floor muscle exercise (at home) 3) Standard care 	1) Intestinal function (Chinese version of MSKCC intestinal function questionnaire)	<p>Intestinal function of the biofeedback group was significantly better than the control or pelvic floor muscle exercise group for total score and each dimension (P<0.05).</p> <p>No safety data reported.</p>	<p>Well randomised. Unclear if sample was powered. Quite high dropout (17/126) and unclear if analysis took this into account.</p> <p>No objective outcome measures.</p> <p>Compliance in pelvic floor exercise group was not assessed.</p>
Savas 2024	RCT	Paediatric oncology patients (age 6-12) having port needle insertion (n=62) and their mothers.	<ol style="list-style-type: none"> 1) BioVirtualPed (respiratory biofeedback-based VR game) during needle insertion. 2) Standard care. 	<ol style="list-style-type: none"> 1) Pain (Wong-Baker scale) 2) Fear (Child Fear Scale) 3) Anxiety (Children’s State anxiety) 4) Satisfaction (VAS) 5) Respiratory rate 	<p>Significant reduction in pain compared to control group (p < 0.001). Post-procedure fear and anxiety scores were lower in the intervention group (p < 0.001 and p < 0.001, respectively). The intervention group’s mean respiratory rates were lower (p < 0.001), and their satisfaction scores were higher (p < 0.001).</p> <p>No safety data.</p>	<p>Sample was powered. Good description of randomisation.</p> <p>Study was registered.</p>

Tsai 2007	RCT	Patients with advanced cancer (n=37)	1) Biofeedback assisted relaxation training. 6 sessions over 4 weeks. 2) Standard care	1) Pain (BPI) 2) Frontal muscle EMG	Significant reductions in pain intensity ($p < .001$) and EMG ($p = 0.021$) compared to control group. No safety data reported.	Small sample (probably underpowered), with high dropout (13/37), including 3 who refused to continue with intervention. No description of randomisation.
Yoshida 2018	Non-randomised prospective cohort study	Men undergoing robot-assisted radical prostatectomy (RARP) (n=116)	1) Transperineal ultrasound visualised pelvic floor muscle training (PFMT). Performed by physiotherapist and nurse. One month prior to RARP, immediately after catheter removal, and 1 month after RARP. 2) Verbal instruction on PFMT (without ultrasound) at T2 only	Continence recovery (self-reported number of days requiring a pad)	Mean time to continence recovery was significantly shorter in ultrasound group ($p = 0.037$), and postoperative continence status ($p = 0.017$) No safety data reported.	Group allocation was by preference which biases the results. No sample size calculation. Unequal group sizes.