Table 1: Controlled clinical trials of biofeedback for cancer

Source: Lorenc, A, CAM-Cancer Consortium. Biofeedback [online document]. http://cam-cancer.org/en/biofeedback, November 2020.

First author, year	Study design	Participants (number, diagnosis)	Interventions (experimental treatments, control)	Main outcome measures	Main results	Comments (risk of bias, critical evaluation, etc)
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.	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.
De Lira (2019)	RCT	Men undergoing radical prostatectomy for prostate cancer (n=31)	1) Pelvic floor muscle training (perioperative) (physical therapist- guided sessions, including exercises and electromyographic biofeedback) 2) Usual care	1) Urinary incontinence (International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF)) 2) Erectile dysfunction (International Index of Erectile Function (IIEF-5))	No significant difference in incontinence (frequency, severity or impact on QoL) between groups 3 months after surgery.	Powered sample, well randomised, and no loss to follow up.

Gruber, 1993	RCT	Breast cancer patients recently undergone radical mastectomy (n=13)	1) Relaxation, guided imagery and biofeedback 2)Waiting list	1) Natural killer cell activity (NK) 2) Concanavalin A responsiveness (Con-A) 3)Mixed lymphocyte response (MLR) 4) Interleukin II 5) Peripheral blood lymphocytes (PBL) 6) Minnesota Multiphasic Personality Inventory (MMPI), 7) Millon Behavioral Health Inventory (MBHI), 8) Sarason Social Support Scale 9) Rotter Locus of Control 10) QoL (Affects Balance Scale (ABS) and Greer Mental Adjustment to Cancer (MAC) scale).	Significant effects in NK activity ($p<0.017$), MLR ($p<0.001$), Con-A ($p<0.001$) and PBL ($p<0.01$). No significant psychological changes.	Small and likely underpowered. No details of randomisation. No simultaneous control group so possibility of time/season related bias.

Kye (2016)	RCT	Rectal cancer patients with sphincter-saving surgery (n=56)	1) Biofeedback therapy after surgery, during the temporary stoma period. 1 or 2 times/week. 2) Recommendation to do conservative self-rehabilitation e.g. Kegel (also given to group 1)	1) Anorectal manometry; 2) Transanal ultrasound 3) Subjective anorectal function (Cleveland Clinic Incontinence Score)	Significant difference in the change of mean resting pressures between biofeedback and control group (p=0.002). No difference in any other measures of anorectal dysfunction.	Powered sample size, good randomisation. Good detail about follow up/drop outs. Little information on what the biofeedback intervention actually involved, who ran the intervention etc. This is an interim analysis only
Liu (2019)	RCT	Patients with middle and low rectal cancer (n=126)	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)	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).	Well randomised. Unclear if sample was powered. Quite high dropout (17/126) and unclear if analysis took this into account. No objective outcome measures. Compliance in pelvic floor exercise group was not assessed.

Sahin (2016)	RCT	Total laryngectomized laryngeal cancer patients (n=26)	1) Classical method of oesophageal speech therapy 2) Same as group 1, plus online oesophageal multichannel intra-luminal impedance (MII) biofeedback. Simplified animation of air movements. Both interventions were performed by a speech therapist and both groups had the MII catheter inserted. 11 sessions over 6 months.	Speech proficiency (perceptual evaluation of oesophageal speech level)	Both groups had significant improvement in oesophageal speech quality but no difference between groups.	No sample size calculation and likely underpowered. No details of randomisation.
Schwenk, 2016	RCT & proof-of-concept study	Older cancer patients with chemotherapy-induced peripheral neuropathy (n=22)	1) Sensor-based balance training (interactive and game-based using wearable sensors). Two sessions per week for 4 weeks. 2) Usual care.	1) Changes in sway of ankle, hip and centre of mass (CoM) (balance tests) 2) Gait performance 3) Fear of falling (Falls Efficacy Scale International)	Training was safe and well accepted. Sway of hip and ankle in feet open and sway of hip and CoM were significantly reduced in the intervention group compared to control (p=0.010; 0.022; 0.008; -0.035). No significant difference for tests with eyes closed, or for gait speed or fear of falling.	Unclear if this is a pilot study: the sample size is small and likely underpowered but it is described as an RCT. Single blinded with good randomisation procedure.

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.	Small sample (probably underpowered), with high dropout (13/37), including 3 who refused to continue with intervention. No description of randomisation.
Non randomised but controlled trials						
Liang (2016)	Non-randomised retrospective cohort study	Patients with anterior resection syndrome after low anterior resection for rectal cancer (n=61)	1) Balloon training biofeedback, including strength, coordination and sensory training. 2) Control group (not randomised) were healthy volunteers, argon plasma coagulation patients and haemorrhage patients.	1) Anorectal manometry (Also measured number of bowel movements/day and fecal incontinence , but these were not measured for the control group	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, $P = 0.015$. The number of biofeedback therapy cycles, the use of laparoscopic surgery, and current nonsmoking status might predict for positive therapeutic effects.	This was a cohort study rather than a trial but was well conducted as such. However, as a cohort study it cannot control for time, attention, therapist interaction, or other treatments.

Yoshida, 2018	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)	Group allocation was by preference which biases the results. No sample size calculation. Unequal group sizes.