

Table 1: Controlled clinical trials of reflexology for cancer

Source: Ava Lorenc, Helen Cooke, CAM-Cancer Consortium. <u>Reflexology [online document]</u>. March 2019

Outcome	First author (year) [ref]	Study design	Participants (number, diagnosis)	Interventions (experimental treatments, control)	Main outcome measures	Main results	Comments
Anxiety	Quattrin (2006) [15]	Non- randomised CT (Pre-test, post-test comparative group)	Hospitalised people receiving chemotherapy (n=30)	1)Reflexology 2) Control – no intervention	Spielberger State-Trait Anxiety Inventory	A decrease of 7.9 points on the state-anxiety scale in the treatment group and of 0.8 points in the control group (P < 0.0001).	The lack of randomisation, small number of participants and the fact that reflexology treatment was provided by a student nurse rather than by a fully qualified reflexologist, reduced the reliability of the results.
Symptoms and functions of chemotherapy- induced peripheral neuropathy	Kurt and Can (2017) [16]	Pilot RCT	Patients with chemotherapy-induced peripheral neuropathy (CIPN) (various cancers) (n=60)	1) Reflexology 2) Standard care	1) EORTC-CIPN-20 2) Brief pain inventory (BPI) 3) NCI-CTCAE v4.0 toxicity criteria	There was no difference between groups for CIPN symptoms apart from improvement in the sensory functions after the 3rd interview (p=0.024).	Fairly high drop-out. Reflexology delivered by researcher or caregiver – unclear how much/when by each. Blinding unclear.
Quality of life, fatigue, sleep, pain	Tarrasch (2017) [17]	Preference trial	Breast cancer patients undergoing radiation therapy (n=72)	1) Reflexology 2) Control – no intervention	 Multidimensional Quality of Life Scale-Cancer questionnaire (MQOLS- CA), Lee Fatigue Scale (LFS) General Sleep Disturbance Scale (GSDS) Numeric rating scale for pain 	Compared to control, reflexology group had significant lower levels of fatigue after 5 weeks of radiation therapy (p < 0.001), quality of sleep after 10 weeks of radiation treatment (p < 0.05) and no deterioration of quality of life or increase in pain.	Not randomised. Non-powered sample size and small sample. Lack of blinding
Chemo-therapy induced nausea and vomiting and fatigue	Ozdelikara and Tan (2017) [18]	Non randomised controlled trial.	Women with breast cancer receiving chemotherapy (n=60)	1) Reflexology 2) Standard care (nursing care)	1) Brief fatigue inventory 2) Rhodes index of nausea, vomiting and retching (INVR)	Total mean scores of INVR were significantly lower in reflexology group than control group at 1 st and 2 nd measurement, and for distress and development at 3 rd measurement (p < 0.05).	Small sample size and sample size calculation is unclear. Non-random allocation (by day of attendance at clinic) – yet described as randomisation by authors. Baseline scores for INVR were higher in reflexology group.



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Breast cancer specific health- related quality of life, physical functioning, symptoms and safety	Wyatt (2012) [21]	RCT	Women with advanced- stage breast cancer receiving chemotherapy or hormone therapy (n=385)	 1) Reflexology 2) Lay foot manipulation (LFM) 3) Conventional care 	 SF 36 (physical function sub-scale) Functional Assessment of Cancer Therapy-Breast (FACT-B) scale The Brief Fatigue Inventory (BFI) The Brief Pain Inventory-Short Form The Center of Epidemiologic Studies- Depression (CES-D) scale State-Trait Anxiety Inventory Safety data 	Significant improvements in physical functioning found for the reflexology group compared to the control group (p = 0.04). Severity of dyspnoea was reduced in reflexology group vs control group (p < 0.01) and the LFM group (p = 0.02). No differences were found on breast cancer-specific. HRQOL, depressive symptomatology, state anxiety, pain, and nausea. No adverse events were reported.	Results can only be generalised to women with advanced-stage breast cancer. Safety data was collected by the reflexologists and LFM team. Participants may not have reported adverse events to their perceived care givers. Lack of blinding
Physiologic stress, pain and mood	Hodgson and Laffely (2012) [22]	Pilot RCT	Nursing home residents with cancer (n=18)	1) Reflexology 2) Swedish massage to lower extremities	 Salivary cortisol Apparent Affect Rating Scale (APRS) Checklist of nonverbal pain 	Within group comparisons revealed both reflexology and massage associated with statistically significant changes in salivary cortisol and pain (P < .05). When post-treatment values were compared to the baseline values a slight advantage was indicated for reflexology. According to between-group t- tests, no significantly greater improvement in outcomes resulted when the two treatment conditions were compared.	Small sample size. Although participants were randomised to the two groups, they were not randomly selected for participation in the trial from the nursing home, so the results may not be generalisable Lack of blinding
Pain, anxiety	Jahani (2018) [23]	RCT	Patients with metastatic cancer hospitalized in adult haematology ward (n=84)	1) Reflexology 2) Placebo (sole touching)	1) VAS pain scale 2) Spielberger anxiety scale	Pain intensity and anxiety decreased more in the reflexology than control group (p<0.05; p=0.04). No difference in consumption of painkiller drugs.	Little information on the placebo intervention and no non-treatment group. Details of sampling and inclusion criteria are not given. Only patients were blinded.



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Quality of life	Ozdelikara and Tan (2017) [24]	RCT	Women with breast cancer receiving chemotherapy (n=60)	1) Reflexology 2) Standard care (nursing intervention)	1) EORTC QLQC30 Quality of Life Scale	Patients in the treatment group had significantly lower symptom total scores ($p = 0.001$) and significantly higher functional and general health scores ($p = 0.000$) than control group.	Small sample size and sample size calculation is unclear. Randomisation method is unclear. Doesn't appear to be blinded.
Healthcare service utilization and work-related productivity	Luo (2018) [25]	RCT	Women with advanced breast cancer (n=256)	1) Reflexology 2) Attention control	 Conventional Health Service and Productivity Costs Form (CHSPCF) World Health Organization Health and Work Performance Questionnaire (HPQ) 	Patients in the reflexology group were less likely to have hospital visits compared to the control group in both weighted/unweighted and unadjusted/adjusted logistic regressions. Reflexology group also had lower relative absenteeism in the unweighted adjusted analysis and less absolute presenteeism in weighted unadjusted analysis.	High dropout (although analysis did take this into account). Short-term follow up.
Various symptoms	Wyatt (2017) <mark>[</mark> 26]	RCT	Breast cancer (n=256 patient-carer dyads)	 1) Reflexology (caregiver-delivered) 2) Attention control 	 M.D. Anderson Symptom Inventory (MDASI) Patient Reported Outcomes Measurement Information System (PROMIS) (physical functioning and satisfaction with participation in social roles) Quality of Life Index Multidimensional Scale of Perceived Social Support Tool Quality of Relationship Tool 	Significant reductions in average symptom severity (p=0.02) and interference (p<0.01) over 11 weeks in the reflexology group compared to control. No group differences in functioning, social support, quality of relationship or satisfaction with life at weeks 5 and 11. Reductions in symptom were reduced at week 11 compared to weeks 2-5	High attrition rates.

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Pain, fatigue, quality of life	Dikmen (2018) [27]	RCT	Adults with gynaecologic cancer (n=80)	 1) Reflexology 2) Progressive muscle relaxation (PMR) 3) Reflexology + PMR 4) Control (no details given) 	 Brief Pain Inventory Brief Fatigue Inventory Multidimensional Quality-of- Life Scale 	Reporting of (between group) results is unclear - it is not possible to draw any conclusions about reflexology in comparison to either PMR or control group. Patients reported no adverse effects or harm after the interventions.	Reporting has many limitations e.g. no details on what control group received, no significant differences for QoL yet authors conclude the interventions improve QoL, and numbers in flow chart don't add up. Baseline differences in pain scores were not adjusted for, analgesia use was not controlled for, Sample size powered but quite high loss to follow-up. Patients and researchers were blinded.
Quality of life, adverse effects of cancer treatment	Uysal (2017) [28]	RCT	Colorectal cancer patients receiving chemoradiotherapy (n=60)	1) Classical foot massage 2) Reflexology 3) Standard care	1) EORTC quality of life questionnaires C30 and CR29. 2) Adverse effects of cancer treatment	Compared to control, reflexology group had significantly lower pain incidence at grade 2+ (4 th week p= 0.002 and 5 th week p<0.001), and significantly better function and global health scores (3 rd and 5 th week p<0.001). Compared to both massage and control, reflexology group had significantly lower fatigue (3 rd / week p=0.030 4 th week p<0.001, 5 th week p=0.030 and symptom scale scores (5 th week p<0.001). The weekly changes in dysuria, sore skin, mucus in stool, stool frequency, urinary incontinence, trouble with taste, embarrassment by bowel movement, and impotence symptoms of all 3 groups were not significantly different	Randomisation not described. Data only collected during and at end of intervention (no follow-up). Not blinded.

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Self-selected problems concerns/ symptoms	Dyer (2013) [29]	RCT	Adults outpatients with cancer (n=115)	1) Reflexology 2) Aromatherapy	1) Measure Yourself Concerns and Wellbeing (MYCaW) 2) VAS (relaxation)	Majority of the first concerns were physical (unspecified) in both groups: 59% aromatherapy group, 49% reflexology group. Both reflexology and aromatherapy massage found to be effective for MYCaW first concerns (p = 0.046). Difference in mean change between groups 0.453 in favour of aromatherapy massage (standard error of the mean 0.323). No statistical difference between groups for MYCaW second concerns or overall well-being scores, proportions of patients gaining clinical benefit, VAS scores over time (p = 0.489) or between groups (p = 0.408) or in written responses.	Limitations include lack of an untreated control group and lack of blinding.
Immune function/response	Green (2009) [30]	RCT	Women with early breast cancer (post surgery) (n=183)	1) Self-initiated support (SIS) 2) SIS plus reflexology 3) SIS plus scalp massage	A variety of biological assays which measured host defences and endocrine function.	Scalp massage (active control condition), but not reflexology, induced a range of immunological changes including an increase in the % of CDCD25+ cells and a shift towards a Th1-like response.	Neuro-endocrine factors were only measured at a single-time rather than at different times of the days to account for circadian rhythms. Lack of blinding.