Title: Green tea and green tea extract in oncological treatment: a systematic review
Journal: International Journal for Vitamin and Nutrition Research
Authors: Fanny Wiese, Sabine Kutschan, Jennifer Doerfler, Viktoria Mathies, Jens Buentzel, Judith Buentzel, Jutta Huebner
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Electronic Supplementary Material 2, https://doi.org/10.1024/0300-9831/a000698

Electronic supplementary material 2. Evidence tables

Reference	Study type	Patient characteristics	Intervention/ Control, observation	Examined endpoints	Key findings	Adverse Events/Interactions	Founding/ Conflicts of interest	Methodological comments	Evidence class (Oxford)
Crew (2012): Phase IB Randomized, Double-Blinded, Placebo-Controlled, Dose Escalation Study of Polyphenon E in Women with Hormone Receptor-Negative Breast Cancer. Cancer Prevention Research (Philadelphia, Pa.).	multicentric double-blinded randomized 4 arms number of participants included: N=40 (evaluated: N=40, intent-to-treat; drop-out: N=6) USA (Houston and New York), July 2007 to August 2009	breast cancer (estrogen and progesterone receptor negative, stage I-III (not metastasized), last CTx, RTx or surgery at least 6 months ago gender: 100 % female age: median=52, range=36-64	**Arm A:** N=16, polyphenon E capsule, including 400mg EGCG, 2 x daily, for 6 months **Arm B:** N=11, polyphenon E capsule, including 600mg EGCG, 2 x daily, for 6 months **Arm C:** N=3, polyphenon E capsule, including 800mg EGCG, 2 x daily, for 6	T0: baseline, T1: after 6 months **Primary endpoints:** 1. maximum tolerated dose (toxicity level of 25% of participants with toxicity ≥ grade II according to CTCAE) Preclinical outcomes were also assessed.	1. dose-limiting toxicities: arm A: 6.25% (grade III rectal bleeding - day 18), arm B: 27% (grade II weight gain - day 138, grade III indigestion - day 40, grade III insomnia - day 6), arm C: 33% (grade III transaminase elevation (ALT) - day 91) The rectal bleeding occurred in a woman with pre-existing	registration: using the CTCAE no significant differences between groups A+B+C and D number of side effects (number of affected patients in %): **Arm A+B+C:** nausea: 8 (27) diarrhea: 3 (10) constipation: 3 (10) indigestion: 10 (33) abdominal pain: 1 (3) flatulence: 1 (3) gastrointestinal bleed: 1 (3) weight gain: 1 (3) palpitations: 1 (3) dyspnea: 0 (0) cough: 0 (0) transaminitis: 3 (10)	P. Brown (co-author) is a Consultant/Advisory Board member of Susan G. Komen for the Cure (breast cancer organization USA) no potential CoI were disclosed by the other authors	**PRO:** multicenter Study ethics vote wash-out and control of confounding factors: no tea and limited caffeine consumption prior to study initiation until end of the study use of TITE-CRM (time-to-event continual reassessment method) and thus also recording of long-term (6 months) effects **CONTRA:**	2b

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			months **Arm D:** N=10, Placebo, no information, except "matching"		diverticulosis with hospitalization. There upon change of protocol with exclusion of women with gastrointestinal bleeding in their history.	hyperbilirubinemia: 0 (0) high alkaline phosphatase: 2 (7) high lipase: 2 (7) hyperuricemia: 1 (3) proteinuria: 3 (10) anemia: 2 (7) headache: 2 (7) confusion: 0 (0) insomnia: 4 (13) irregular menses 1 (3) hot flashes: 1 (3) flushing: 0 (0) vaginal symptoms: 0 (0) **Arm D:** nausea: 2 (20) diarrhea: 2 (20) constipation: 0 (0) indigestion: 2 (20) abdominal pain: 2 (20) flatulence: 1 (10) gastrointestinal bleed: 0 (0) weight gain: 0 (0) palpitations: 1 (10)		measurement of hormonal side effects such as irregular menses rather difficult, since postmenopausal women included in the study intent-to-treat analysis for AE leads to the fact that AE can be underestimated statistical comparison of AE not separated by dose and grade no statistical comparison of group comparability to the baseline regarding demographic	

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						dyspnea: 1 (10) cough: 1 (10) transaminitis: 0 (0) hyperbilirubinemia: 1 (10) high alkaline phosphatase: 0 (0) high lipase: 0 (0) hyperuricemia: 1 (10) proteinuria: 1 (10) anemia: 0 headache: 2 (20) confusion: 1 (10) insomnia: 0 (0) irregular menses: 1 (10) hot flashes: 0 (0) flushing: 1 (10) vaginal symptoms: 1 (10) overall, mainly grade I AE in the gastrointestinal tract		variables (in group A+B+C 47% of patients were stage I and 30% stage II, in group D 20% stage I and 60% stage II)	
Emami (2014): Double-blinded, randomized,	prospective monocentric	standardized radiation with 5000cGy	**Arm A:** N=21, green tea tablet	**Primary endpoints:** 1. frequency	1. week 2: no difference in frequency	according to statement no AE	according to statement no CoI	**PRO:** ethics vote	2b

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placebo-controlled study to evaluate the effectiveness of green tea in preventing acute gastrointestinal complications due to radiotherapy. Journal of research in medical sciences: the official journal of Isfahan University of Medical Sciences.	double-blinded
	
	randomized
	
	2 arms
	
	number of participants included: N=42 (number of participants evaluated: N=42)
	
	Iran, February 2013 to September 2013
		(1000cGy weekly) for patients with pelvic and abdominal malignancy (prostate, uterus, cervix, bladder, rectum and colon); cancer type and stage: no information
		
		RTx, CTx, postoperative
		
		gender: 45% female
		
		age:
		arm A: mean=65.7, SD=9.3;
		arm B: mean=58.7, SD=13.6;
		common mean=62.2
			oral, 450mg, 1 x daily for 5 weeks during irradiation
			
			Arm B: N=21, placebo tablet, intake see above
				and severity of diarrhea (frequency with diary, classification of severity by CTCAE)
				
				2. frequency and severity of vomiting (frequency with diary, classification of severity by FLIE)
				
				daily recording by diary (number, consistency of feces, occurrence of symptoms such as nausea, vomiting and gastrointestinal cramps) from
					without diarrhea, arm A: N=16, arm B: N=18 (p=0.4);
					week 3-5: significantly lower frequency of diarrhea in arm A compared to arm B,
					week 3: without diarrhea, arm A: N=14, arm B: N=9 (p=0.04)
					week 4: without diarrhea, arm A: N=16, arm B: N=7 (p=0.002)
					week 5: without diarrhea, arm A: N=17, arm
								comparability of groups is given
								
								power analysis performed and criteria met
								
								CONTRA:
								small sample size
								
								no test for normal distribution
								
								no detailed information on randomization process
								
								missing demographic data (initial diagnosis, drug use, comorbidities, previous experience with etc.)
								
								very short	

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				the 1st day of the 2nd week until the end of the 5th week	B: N=8 (p=0.002) 2. no significant difference between both arms and/or time			reporting with few details and inconsistencies, statistical results not comprehensible and interpretation of results by authors incorrect and misleading	

Henning (2015): Randomized Clinical Trial of Brewed Green and Black Tea in Men With Prostate Cancer Prior to Prostatectomy. The Prostate.	prospective
	
	multicentric
	
	open label
	
	randomized
	
	3 arms
	
	phase II
	
	number of participants included: N=113 (number of
		prostate adenocarcinoma
		
		preoperative (radical prostatectomy)
		
		gender: 100% male
		
		age:
		arm A: mean=62.1, SD=6.9;
		arm B: mean=61.4, SD=7.4;
			Arm A:
			N=34,
			6 cups of green tea per day, including 562mg EGCG, until surgery (mean duration=33 days)
			
			Arm B:
			N=26,
			6 cups of black tea per day, including 28mg EGCG, until
				T0: baseline,
				T1: post-intervention
				
				Secondary endpoints:
				1. serum PSA levels
				
				Furthermore, prostate tumor markers were collected as the primary endpoint and urine oxidation, tea polyphenol
					1. mean ± SD; decrease in serum PSA levels higher in arm A compared to arm C (p=0.04), PSA in arm A (N=30): T0:9.6±5.2 to T1:8.4±4.3 vs. arm C (N=30): T0:9.9±8.5 to T1:10.0±9.0;
					
					no significant difference in
						according to statement there were no serious AE related to the interventions, no information regarding the recording	grand sponsor: NIH
							
							according to statement no potential CoI
								PRO:
								ethics vote
								
								multicentric study
								
								comparability of groups is given
								
								wash out and control of confounders: subjects were instructed to abstain from all teas and tea containing products other
									2b

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	participants completed the intervention: N=93; attrition: N=9 in arm A, N=7 in arm B, N=4 in arm C) USA (Los Angeles), 2008-2012	arm C: mean=62.8, SD=6.2; common mean=62.2; range=40-70	surgery (mean duration=31 days) **Arm C:** N=33, 6 cups of water per day, until surgery (mean duration=29 days)	uptake in prostate tissue and urine as another secondary endpoint of the study.	changes between arm B and arm C, p>0.05: PSA arm B (N=23): T0:9.2±4.3 to T1:9.6±6.0 vs. arm C (N=30) see above			than the study tea and stop nutritional supplements and herbal therapies (i.e. lycopene, selenium, vitamin E, fish oil, and saw palmetto) control of adherence (diary entries: arm A=95%, arm B=92%, arm C= 93%) polyphenol composition of brewed tea determined by HPLC power analysis testing for normal distribution,	

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								consideration of the possibility of α cumulation through multiple testing and adequate application of statistical methods **CONTRA:** not blinded evaluation per-protocol inconsistencies regarding group size for PSA levels (apparently not all evaluated, no information on missing data) high attrition multiple endpoints, the overall false	

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								detection rate was 10.8%.	
Kessels (2017): Topical sinecatechins, 10%, ointment for superficial basal cell carcinoma: a randomized clinical trial. JAMA dermatology.	monocentric double-blinded randomized 2 arms number of participants included: N= 42 (drop-out: N= 3) Netherlands, Jan 2014- May 2016	superficial basal cell carcinoma preoperative gender: no information age: no information	**Arm A:** N=21, topical sinecatechin ointment, 10% with 55-72mg EGCG per 1g ointment (applied twice a day for 6 weeks by patients themselves) **Arm B:** N=21, placebo ointment, application see above	T0: baseline, T1: after 3 weeks, T2: after 6 weeks, T3: after 8 weeks (directly before surgery) **Primary endpoints:** 1. percentage of patients with no tumors by histological examination (T3) 2. size of the tumor (T1, T2, T3) Preclinical outcomes were also assessed.	1. no significant difference between the arms (arm A: 1 case (5%), arm B: 2 cases (10%), p>0.99) To 2. No significant difference between the arms (p=0.15)	data acquisition by doctor and weekly diary entries of the patients: in arm A significantly higher frequency of moderate to serious erythema (To T1/T2/T3 in %: arm A: 10/12/9, arm B: 6/2/2), edema (arm A: 2/6/3, arm B: 0/0/0), erosion (arm A: 5/7/4, arm B: 1/0/0), crusts (arm A: 3/10/6, arm B: 2/0/0) and itching (arm A: 10/13/12, arm B: 3/0/1)	according to statement no CoI This study was supported in part by Willpharma BV, which supplied study medication (sinecatechins ointment, 10%, and placebo ointment). The sponsor was not involved in the design and implementation of the study.	**PRO:** ethics vote power analysis performed and criteria met 1-week wash-out of green tea before the start of the study control of co-interventions (no further consumption of green tea, immunosuppressive medication) control of adherence **CONTRA:** no information about demographic data and comparability of the arms at baseline	2b

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Reference	Study type	Patient characteristics	Intervention/ Control, observation	Examined endpoints	Key findings	Adverse Events/Interactions	Founding/ Conflicts of interest	Methodological comments	Evidence class (Oxford)
								unclear whether intention-to-treat analysis	
Lian (2014): Comparing the effectiveness of green tea versus topical metronidazole powder in malodorous control of fungating malignant wounds in a controlled randomised study. Proceedings of singapore healthcare. RefID	prospective monocentric blinding: no information (probably not blinded) (block-) randomized 2 arms number of participants included: N=30 (number of participants completed the intervention: N=29; attrition: N=1	malodorous fungating malignant wounds gender: 90% female age: arm A: median=55, range=33-81; arm B: median=46, range=35-81	**Arm A:** N=15, green tea, daily dressing for 7 days, irrigate wound with green tea solution (1 tea bag to 250ml boiling water for 10 minutes), cover wound with absorbent pad with dry green tea bag (1 to 50cm^2-1 green tea bag, 51 to 100cm^2-2 green tea bags) and secure with tape A**rm B**: N=15, metronidazole	**Primary endpoints:** 1. malodorous of wounds: measurement tool was VNS (0=“no smell“ and 10=“the worst smell that one can imagine“), using by patient and nurse independently daily 2. QoL: measurement with a five-item questionnaire which was rated on a VNS (0 being the healthiest	1. reduction in malodorous score in all patients showed within seven days of treatment, no significant difference in the improvement of odor between both arms in self- and nurses' assessment, (p>0.05) 2. improvement in odor control in all patients showed after day 7 (p=0.00), impairment of daily life (p=0.00),	no AE reported, no information on the recording of AE (probably only reporting)	study was funded by Ministry of Health Nursing Research Committee	**PRO:** ethics vote power analysis performed and criteria met block-randomization by sealed opaque envelops (by a research assistant) wash out: patients receiving systemic metronidazole or patients treated with topical metronidazole for more than 30 days were excluded control of confounders (like	2b

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	in arm A, patient died on day 5) Singapore, November 2005 to October 2008		powder, daily dressing for 7 days, irrigate wound with normal saline 0.9%, sprinkle metronidazole powder to wound bed (1 to 50cm^2-400mg metronidazole, 51 to 100cm^2-800mg metronidazole), cover wound with absorbent pad and secure with tape	attribute and 10 being the worst), performed on day 1 and day 7 3. healing progress: measurement by taking a picture using a digital camera, performed on day 1 and day 7	physical complaints (p=0.00), appetite (p=0.00) and social activities (p=0.00); no significant differences between the two arms (p>0.05), except for Q5 (interference of odor with social activities) in favor of arm A on day 1 (p=0.04) 3. no statistical significance between both arms (p>0.05) note: eight patients in arm A reported having 'cooling' effect on the wound bed after cleansing with the green tea			wound size, necrotic tissue and necrotic amount): characteristics of wounds in both groups were comparable (except patients in arm A have significantly larger wound sizes) to maintain internal consistency of data collection, all data collectors attended structured training sessions conducted by the principal investigator intention-to-treat analysis **CONTRA:** small sample size probably not blinded (no information)	

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					fluid			group comparability not sufficiently given, difference at baseline: larger wounds in arm A compared to arm B ($p<0.04$) tool for assessing QoL not validated and may lead patients to more positive answers	
Nguyen (2012): Randomized, double-blind, placebo-controlled trial of polyphenon E in prostate cancer patients before prostatectomy: evaluation of potential chemopreventive	prospective mono- or multicentric: no information double-blinded randomized 2 arms	prostate cancer preoperative (radical prostatectomy) gender: 100% male age: arm A: mean=63.4, SD=5.9;	**Arm A:** N=25, polyphenon E (containing 800mg EGCG), 4 capsules (each 200mg EGCG) each morning with food **Arm B**: N=25,	T0: baseline, T1: post-intervention **Secondary endpoints:** 1. serum PSA Furthermore, bioavailability of green tea polyphenols in	1. PSA values showed a greater reduction in arm A than in arm B, but these were not statistically significant (arm A: -0.66±2.56ng/ml, arm B: -0.08±1.28ng/ml, p=0.26);	description and grading by NCI CTCAE version 3.0, frequency by diary entries AE were all grade I or II events a total of 18 (arm A) and 39 (arm B) AE occurred, summary of AE occurring in greater than	according to statement no potential CoI This work was supported by a contract from the National Cancer Institute and the Arizona Cancer Center Support Grant. The costs of	**PRO:** ethics vote group comparability is given wash out: patients were excluded if they drank tea regularly within 1 month of enrollment	2b

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activities. Cancer prevention research (Philadelphia, Pa.). RefID	number of participants included: N=50 (number of participants completed the intervention: N=48; attrition: N=1 in each arm, surgery cancelled, drop-out: 2-23% missing data) USA, March 2007 to July 2010	arm B: mean=61.3, SD=5.7; common mean=62.35	placebo, intake see above duration: for 3 to 6 weeks before surgery	prostate tissue after intervention (as actually the primary endpoint of the study), plasma concentration and other systemic and tissue biomarkers were assessed.	N (%), PSA reduction arm A: 14 (58.3), arm B: 8 (36.4), no significant group difference (p=0.15)	4% of subjects in arm A and arm B, regardless of attribution (number of AE (number of patients affected in %)): **Arm A:** nausea: 4 (16) diarrhea: 2 (8) headache: 1 (4) fever: 0 (0) body ache: 0 (0) muscle ache: 0 (0) **Arm B:** nausea: 4 (16) diarrhea: 5 (20) headache: 2 (8) fever: 3 (12) body ache: 2 (8) muscle ache: 2 (8)	publication of this article were defrayed in part by the payment of page charges.	control of therapy adherence (capsule count and intake calendar) testing the normal distribution of data and applying adequate tests **CONTRA:** small sample size (post-hoc power analysis performed and criteria not met) intention-to-treat analysis of AE (possible underestimation of AE) per-protocol analysis of endpoints unclear randomization process	

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								no correction for multiple testing for comparison between groups for changes no information about location (hospital vs. at home vs. hospice) of survey no explanation for blinding	
Stendell-Hollis (2010): Green tea improves metabolic biomarkers, not weight or body composition: a pilot study in overweight breast cancer survivors. Journal of human nutrition and dietetics: the	pilot-study prospective mono- or multicentric: no information double-blinded randomized 2 arms	breast cancer survivors overweight/obese (BMI= 25-40kg/m^2) completion of initial treatment for early invasive breast cancer (I-III) at least 12 months prior to, and no	**Arm A:** N=29, green tea, decaffeinated, 960ml daily (=4 bags, containing 128.84mg EGCG); 1 tea bag added with 240ml water and steep for 3 min.	T0: baseline, T1: after 6 months **Primary endpoints:** 1. body weight: measurement by using standardized protocols 2. body composition	1. arm A: mean body weight was reduced by 1.2kg at T1, arm B: mean body weight was slightly rise by 0.2kg at T1, these differences were not statistically significant (p=0.23)	no information on AE abortion of 4 test persons due to intolerance or not ability of tea (not clear which group)	authors declare they have no CoI to report The work was supported by the National Susan G. Komen Foundation (Breast Cancer Organization) and the Arizona Cancer Center.	**PRO:** ethics vote run-in period control of adherence (by using daily tea logs and counting of used and unused tea bags, adherence very high with > 94% in both groups)	2b

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official journal of the British Dietetic Association. RefID	number of participants included: N=54 (number of participants completed the intervention: N=39; attrition: N=6 in arm A, N=9 in arm B) USA, period: no information	more than 10 years prior to, enrolment in the study gender: 100% female age: arm A: mean=56.6, SD=8.1; arm B: mean=57.8, SD=8.5; common mean=57.1, SD=8.2	A**rm B**: N=25, placebo, citrus-based herbal tea, intake see above, does not include EGCG duration: 6 months	(BMI, body fat): measurement by using dual energy X-ray absorptiometry (DXA) in accordance with standardized procedures Furthermore, metabolic parameters and lipid profiles were collected.	2. arm A: BMI was reduced by 0.5kg/m^2 at T1, body fat was reduced by 0.6% at T1, arm B: BMI has remained the same, body fat was slightly rise by 0.4% at T1, these differences were not statistically significant (p=0.22 for BMI, p=0.21 for body fat)			testing taste comparability of tea varieties (even if only with N=6) control of general food intake via AFFQ and inclusion in analysis testing for normal distribution of the data (baseline) **CONTRA:** small sample size high attrition per-protocol analysis	

AE Adverse Events, *AFFQ* Arizona Food Frequency Questionnaire, *ALT* Alanin-Aminotransferase, *BMI* Body-Mass-Index, *CoI* Conflicts of Interest, *CTCAE* Common Terminology Criteria for Adverse Events, *CTx* Chemotherapy, *FLIE* Functional Living Index Emesis, *HPLC* High Performance Liquid Chromatography, *NCI* National Cancer Institute, *NIH* National Institutes of Health, *PSA* Prostate-Specific Antigen, *QoL* Quality of Life, *RTx* Radiotherapy, *VNS* Verbal Numerical Scale