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Efficacy of Teavigo[®] in the area of weight management

In the Chinese tradition green tea is said to wash out fat. Green tea catechins, in particular EGCG, are ingested in considerable amounts through consumption of green tea beverages, especially in Asia. For instance, the average daily intake of EGCG in Japan is in the range of 120 – 383mg for men and 107 – 339mg EGCG for women. (Tsubono et al. 1997)

Epidemiological evidence shows that subjects with habitual consumption of green tea for more than ten years were characterized by a lower percentage of total body fat, smaller waist circumference and decreased waist-to-hip ratio.(Wu et al 2003) These findings are supported by data showing that green tea, green tea catechins and EGCG are efficacious in cell and animal models of obesity.(Wolfram et al 2006) In addition, a number of human intervention studies showed a reduction in body weight and body fat in response to green tea and green tea extract. The reduction in body weight ranged from 1.1 kg to 3.5 kg, and the loss in body fat ranged from 0.7 kg to 1.8 kg (see table below).

Citations	Type of study	Population	Test components (daily dosage)	Duration of intake	Main outcomes		
					Weight (kg)	Fat mass (kg)	BMI
Chantre et al.	Multi-center,	7 M, 63 F	GTE (375 mg catechins, of which 270 mg was	12 weeks			
2002	open, uncontrolled	BMI: 28.9	EGCG)		-3.5	Not reported	Not reported
Hase et al. 2001	Case control	23 M BMI: 24-25	Control (118.5 mg catechins, of which 32 mg was EGCG and 75 mg caffeine) GTE (483.0 mg catechins, of which 300 mg was EGCG and 75.5 mg caffeine)	12 weeks	-0.5	-1.7	-0.6
Kajimoto et al.	Double blind	98 M, 97 F	Control beverage (41 mg catechins, of which 9	12 weeks	Green tea b	everage, low	
2006	three parallel arm, controlled	BMI: 25.7	mg was EGCG and 52 mg caffeine) Green tea beverage, low (444 mg catechins, of		-1.1*	-3.9%*	-0.4*
			Green tea beverage high (646 mg catterne)		Green tea b	everage, high	
			which 224 mg was EGCG and 49 mg caffeine)		-1.2*	-3.9%*	-0.4*
Kovacs et al. 2004	Randomized parallel, placebo controlled	26 M, 78 F BMI: 25-35	Control (placebo) GTE (573 mg catechins, of which 323 mg was EGCG, and 104 mg caffeine)	13 weeks	0.6	0.5	0.2
Nagao et al. 2007	Multi-center, Randomized, double-blind	140 M, 100 F BMI:26.8	Control beverage (96 mg catechins, of which 16 mg was EGCG and 75 mg caffeine) Green tea beverage (583 mg catechins, of which 100 mg was EGCG and 72 mg caffeine)	12 weeks	-1.6*	-1.8*	-0.6*
Nagao et al. 2005	Double blind, controlled	35 M BMI: 24.9-25.0	Control (oolong tea containing 3 mg EGCG and 78 mg caffeine)	12 weeks at low			
			GTE (690 mg catechins, of which 136 mg was EGCG, and 75 mg caffeine)	calorie diet	-1.1*	-0.7*	-0.4*
Tsuchida et al. 2002	Randomized, double-blind, controlled	43 M, 37 F BMI: 25.9-26.5	Control (126.5 mg catechins, of which 25.2 mg was EGCG and 81 mg caffeine) GTE (588 mg catechins, of which 115 mg was EGCG and 83 mg caffeine)	12 weeks	-1.3*	-1.4*	-0.5*
Chan et al.	Randomized,	34 obese f, BMI	Capsulated green tea powder (of which was 540	12 weeks			
2006	parallel, placebo controlled	30.9	mg EGCG and 83 mg caffeine)		-1.8	-0.2 %	-0.3
Westerterp-	Randomized,	23 M, 53 F	Low habitual caffeine control		Low babitus	al coffeine	
Plantenga et al. 2005	parallel, placebo	BIVII: 25-35	(placebo)		-2 8*	-2 1*	-0.9*
uii 2000	oonalonou		(placebo)	13 weeks	2.0	2	0.0
			Low habitual caffeine GTE		High habitu	al caffeine	
			(270 mg EGCG and 150 mg caffeine) High habitual caffeine GTE (270 mg EGCG and 150 mg caffeine)		0.3	0.1	0.2
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The effect of green tea, green tea extract, high in EGCG on weight management

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Other studies in humans suggest that the body fat-lowering effects are associated with an increase in thermogenesis and fat oxidation. Several human studies addressed this mechanism (see table below). Basically, all studies demonstrated clear increases in energy expenditure (up to 8%) and fat oxidation (up to 36%).

Effect of green tea, green tea extract, high in EGCG on energy expenditure and fat oxidation

Citation	Type of study	Population	Test components	Duration of intake	Main outcomes
Dulloo et al. (1999)	Randomized, double- blind, placebo controlled, crossover	10 healthy M BMI: 25.1	Control (placebo) GTE (375 mg catechins, of which 270 mg was EGCG, and 150 mg caffeine) Caffeine (150 mg)	1 day	GTE: 24 h energy expenditure increased by 4% ($p < 0,01$), 24 h RQ decreased by 3.4% ($p < 0.001$) due to increased fat oxidation (35%, $p <$ 0.001), urinary norephinephrine increased by 40% ($p < 0.05$)
Komatsu et al. (2003)	Randomized, controlled, cross-over	11 healthy F BMI: 21.1	Control (water) Oolong tea (81 mg EGCG and 77 mg caffeine) Green tea (156 mg EGCG and 161 mg caffeine)	Single administr ation	Control: Cumulative increase in EE of 11.2 \pm 1.1 kJ/2 h Oolong tea: Cumulative increase in EE of 110.7 \pm 17.7 kJ/2 h (p < 0.05) and no significant difference in RQ Green tea: Cumulative increase in EE of 49.5 \pm 0.4 kJ/2 h (p < 0.05) and no significant difference in RQ
Rumpler et al. (2001)	Randomized, cross-over	12 healthy M BMI: 25.9	Control (water) Caffeine (270 mg) Half-strength tea (122 mg EGCG) Full-strength tea (244 mg EGCG)	3 days	Caffeine: 24 h EE increased by 3.4% and fat oxidation by 8% above control (p<0.01) Half-strength tea: 24 h EE increased by 0.5% and fat oxidation by 2% above control Full-strength tea: 24 h EE increased by 2.9% and fat oxidation by 12% above control (p<0.01)
Bérubé-Parent 2005	Randomized, double-blind, placebo- controlled, cross-over	14 healthy men, BMI 20-27	Placebo 600mg caffeine + 270 mg EGCG 600mg caffeine + 600 mg EGCG 600mg caffeine + 900 mg EGCG 600mg caffeine + 1200 mg EGCG	1 day	24-h EE increased by 8% vs placebo and remained rather stable with increasing EGCG conc. (p<0.001) decrease in RQ by 0.02 and increase in fat oxidation by 20 g/d, CHO oxidation remained rather stable
Rudelle et al. 2007	Randomized, double-blind, placebo- controlled, cross-over	31 healthy male and female volunteers, BMI 21.8±1.8	Control Treatment (Caffeine 300 mg, EGCG 282 mg, calcium 633 mg)	3 days	24-h EE sig. increased by 4.6% vs placebo (p=0,002) Fat oxidation increased by 3.2g /24h or (3.3%), not significant CHO oxidation increased by 20g/24h or (6.5%), not significant
Ota et al. 2005	Controlled, parallel	14 healthy men, BMI 23.1-24.5	Control (exercise) Green tea beverage (218 mg EGCG, max 40 mg caffeine) + exercise	8 weeks	EE was non-significantly increased Sedentary fat oxidation and during exercise in conjunction with green tea beverage increased by 36% or 31%, respectively (p=0.02) compared to control

It is worth mentioning that caffeine content in some of the evaluated studies was relatively small (75, 50 or 40 mg). It has been argued that some of the anti-obesity effects of green tea are due to caffeine. However, the majority of literature indicates effects of caffeine on fat oxidation and thermogenesis when \geq 100 mg caffeine is used. Thus it could be deduced that the observed effects on body weight and body fat in the studies by Nagao et al.(2005, 2007), Kajimoto et al.(2006), Tsuchida et al. (2002) as well as on fat oxidation by Ota et al.(2005) are likely to be caused by the green tea catechins.

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The role of Teavigo[®]

Many of the health-promoting effects of green tea are attributed to its catechin content. EGCG is regarded as the most active catechin of green tea. Consequently, DSM conducted own studies with Teavigo[®], pure EGCG. We showed that Teavigo[®] reduced fat mass and prevented diet-induced obesity in animal models of obesity. It exerts its effects via different mechanisms, including inhibited adipogenesis, reduced fat absorption and increased fat oxidation. A tendency to increase fat oxidation was also shown in two human studies with Teavigo[®] (see table below).

Summary of animal and human studies with Teavigo[®] in the area of weight management

Citation	Type of study	Population	Test components	Duration of intake	Main outcomes
Klaus et al. (2005)	Mouse model of diet-induced obesity		Control Teavigo 0,5% Teavigo 1.0%	4 weeks	dose-dependent attenuation of body fat accumulation. Teavigo apparently promoted fat oxidation (not significant)
Wolfram et al. (2005)	rats		Control (water) Teavigo 1.0%	4 weeks	Teavigo decreased body fat accumulation (p<0.05)
Raederstorff et al. (2003)	rats		High fat diet with or without Teavigo	1 day and 4 weeks	Teavigo acutely decreased lipid absorption and increased lipid excretion after 4 weeks (p<0.05)
Thielecke et al. (submitted)	Randomized, double-blind, placebo-controlled, cross-over	10 healthy men, BMI 27-34.9	Placebo 300mg Teavigo 600mg Teavigo 200mg caffeine 300mg Teavigo + 200 mg caffeine	3 days	Teavigo increased fasting and postprandial fat oxidation by 9.9 and 18.5% vs. placebo (statistically not significant)
Hill et al. (2007)	Randomized, double-blind, placebo-controlled	38 female BMI: 31.2	Control (Exercise + Placebo) Treatment (Exercise+ 300 mg EGCG)	12 weeks	Teavigo reduced total body fat (p<0.02), abdominal fat (determined by DXA; p<0.01), intra abdominal adipose tissue (determined by CT; p<0.01), waist circumference (p<0.01) and waist to hip ratio (p<0.01) by wk 12 (statistically not significant between groups)
Boschmann et al. (2007)	Randomized, double-blind, placebo-controlled, cross-over	6 healthy men, BMI: 29.9	Placebo 300mg Teavigo	3 days	Teavigo decreased postprandial RQ by 0.07 suggesting increased fat oxidation (p<0.05)
Thielecke et al. (submitted)	Randomized, double-blind, placebo-controlled	38 female BMI: 31.2	Control (Exercise + Placebo) Treatment (Exercise+ 300 mg EGCG)	12 weeks	EGCG increased fat oxidation during exercise by 36% compared to exercising alone (statistically not significant)

In conclusion, a number of human intervention studies demonstrate a weight and fat reducing effect of green tea or green tea extracts, rich in EGCG. Increased fat oxidation is a major contributor to this overall effect. These findings are supported by studies with Teavigo[®], which exerts anti-obesity effects in in-vitro and animal models of obesity. In addition, a trend of increased fat oxidation in response to Teavigo[®] has also been shown in human studies.

The optimal dose to increase fat oxidation and support a weight management program has not yet been established. The dosage of EGCG used in the various studies evaluated in for this document ranged from 100 mg/day to 540 mg/day, while the duration of the studies varied from 1 day to 13 weeks.