Effectiveness of Ginseng for prevention of colds

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Plain language summary

COLD-FX® is effective for preventing colds in adults. Research findings from 4 experimental studies (randomized controlled trials) that compared COLD-FX® to a placebo (dummy treatment) including over 1000 adults demonstrated a reduction in the risk of getting a cold. In all studies, the COLD-FX® was used in a dose of 400mg/day. The duration of treatment ranged from between 2 months and 6 months.

Relative to placebo, the risk of getting a cold was reduced by about 15% when COLD-FX® was used. The absolute risk reduction was about 6% (this means that if the overall chance of getting a cold is, for example, 50%, then taking COLD-FX® reduces it to 44%). Altogether, 17 people need to be treated to prevent 1 person from getting a cold.

For those who contracted a cold, there was insufficient evidence that the duration or severity was reduced.

This analysis did not explore the effects of age, dose and/or duration of therapy on the effectiveness of COLD-FX®, nor the cost-effectiveness of COLD-FX®.

Short Summary of (limited-scope) review/meta-analysis

Objectives:

To summarize the data regarding the effectiveness of COLD-FX® for cold prevention; specifically, to determine the frequency of individuals experiencing a cold, cold severity, and cold duration.

Literature Search:

No literature search was conducted. The following studies were provided for possible inclusion: McElhaney 2004, 2006, 2011, Predy 2005.

Summary of Included Studies:

Author, Year	Design*	Treatment allocation	Duration of treatment	Participant Age
McElhaney, 2004	DB RCT	400mg/day or placebo	2 months and 3 months***	≥60 years
McElhaney, 2006	DB RCT	400mg/day or placebo	4 months	≥65 years
McElhaney, 2011	DB RCT	400mg/day or placebo**	6 months	≥65 years
Predy, 2005	DB RCT	400mg/day or placebo	4 months	18-65 years

* DB RCT = double-blind randomized controlled trial
** also included an 800mg/day study arm (not included in analysis as all other studies employed 400mg/day; moreover, the Health Canada website information for this product recommends 400mg/day)
*** 2 separate studies reported in one publication

Outcomes for evaluation and Meta-analytic approach:

The following outcomes were considered: frequency of cold, duration of cold, and severity of cold. Different definitions for cold were accepted, as reported and justified in the included studies.

Data were extracted from each article (if/when available) and included in a meta-analysis. Data were summarized using point estimates and 95% confidence intervals (95% CI). The summary statistics included: 1) the (absolute) Risk Difference, RD (rate of individuals with a cold in the COLD-FX® exposed group minus the rate of individuals with a cold in the placebo group), 2) the Risk Ratio, RR (rate of individuals with a cold in the COLD-FX exposed group divided by the rate of individuals with a cold in the Placebo group), 3) mean difference, MD, between groups in the duration of cold, in days, and 4) severity of symptoms, reported using a standardized metric, the weighted mean difference, WMD. All analyses were performed using a random effects model and the Review Manager (5.1) statistical program. A p-value of <0.05 was considered significant. Forest plots have been imported from Review Manager to allow for review/verification of data included in each meta-analysis.

Results:

1) Frequency of individuals experiencing colds

All 4 publications (McEhlaney 2004, 2006, 2011, and Predy 2005) were included in the analysis for this outcome. The study by McEhlaney 2004 contributed to 2 studies in the meta-analysis (due to the inclusion of data from 2 separate studies).

RD: As per Figure 1), RD = -0.06 (95% CI: -0.11, -0.00). This result was significant (p=0.04).

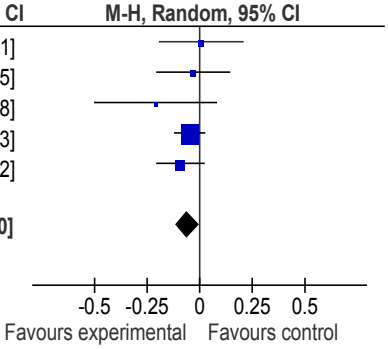
Several additional statistics have been calculated from the RD to facilitate understanding and interpretation of the treatment effects, including: Relative Risk Difference, RRD, and Number Needed to Treat, NNT. The RRD is the RD divided by rate of events in the placebo (control, or unexposed) group. This is the value people are usually referring to when they speak about the magnitude of treatment effects. In this case, there the RRD is 15%. Said another way, there is a 15% reduction in the risk of getting a cold when COLD-FX® is used.

The NNT is the number of people that need to be treated to have (or prevent) one additional outcome of interest; it is calculated mathematically as the reciprocal of risk difference (RD). A large treatment effect leads to a small value for number needed to treat. By calculating NNT, we can apply the results to patients. In this case, the NNT is approximately 17. This means that 17 individuals need to take the product for it to prevent 1 case of a cold.

Figure 1: Risk Difference (RD) Forest Plot for frequency of individuals experiencing a cold

	Experimental		Control			Risk Difference	Risk Difference
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI
McElhaney2004	15	40	18	49	7.6%	0.01 [-0.19, 0.21]	
McElhaney2004a	18	57	18	52	9.9%	-0.03 [-0.21, 0.15]	
McElhaney2006	9	22	13	21	3.6%	-0.21 [-0.50, 0.08]	
McElhaney2011	54	249	67	253	55.5%	-0.05 [-0.12, 0.03]	
Predy2005	71	130	95	149	23.3%	-0.09 [-0.21, 0.02]	
Total (95% CI)		**498**		**524**	**100.0%**	**-0.06 [-0.11, -0.00]**	
Total events	167		211				

Heterogeneity: Tau² = 0.00; Chi² = 1.94, df = 4 (P = 0.75); I² = 0%
Test for overall effect: Z = 2.04 (P = 0.04)

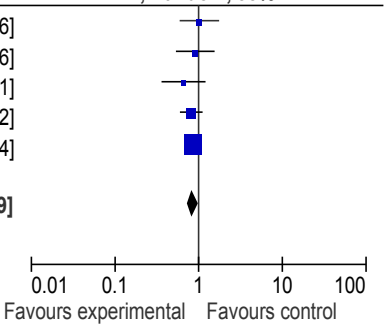


RR: As per Figure 2), RR = 0.85 (95% CI: 0.73, 0.99). This result was significant (p=0.03).

Figure 2: Risk Ratio (RR) Forest Plot for frequency of individuals experiencing a cold

	Experimental		Control			Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI
McElhaney2004	15	40	18	49	7.5%	1.02 [0.59, 1.76]	
McElhaney2004a	18	57	18	52	7.7%	0.91 [0.53, 1.56]	
McElhaney2006	9	22	13	21	6.0%	0.66 [0.36, 1.21]	
McElhaney2011	54	249	67	253	22.5%	0.82 [0.60, 1.12]	
Predy2005	71	130	95	149	56.2%	0.86 [0.70, 1.04]	
Total (95% CI)		**498**		**524**	**100.0%**	**0.85 [0.73, 0.99]**	
Total events	167		211				

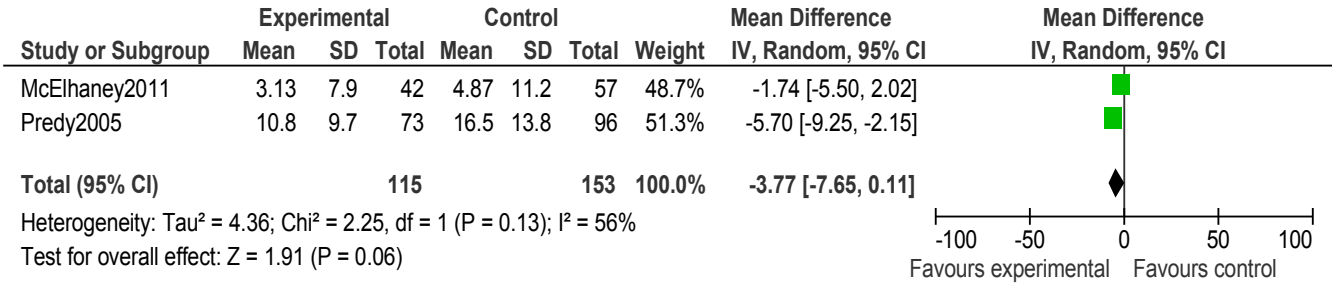
Heterogeneity: Tau² = 0.00; Chi² = 1.23, df = 4 (P = 0.87); I² = 0%
Test for overall effect: Z = 2.15 (P = 0.03)



2) Duration of colds (days)

Two studies were included for this outcome (McElhaney 2011 and Predy 2005). As per Figure 3), the average duration of colds was lower, but did not achieve statistical significance for the COLD-FX® group (p=0.06).

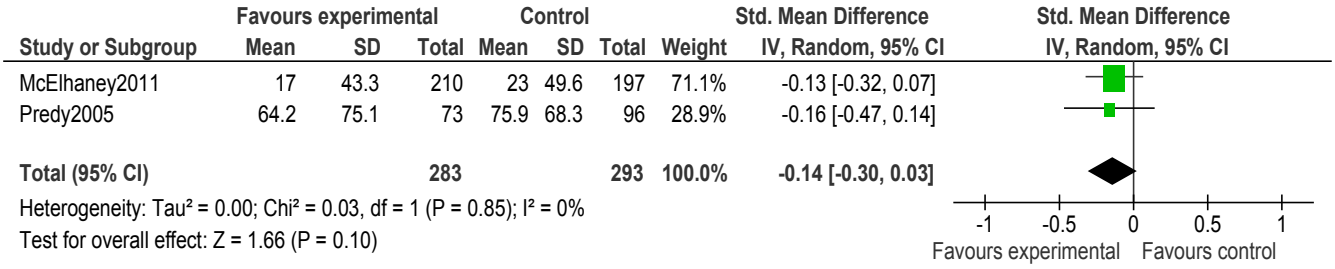
Figure 3: Mean Difference Forest Plot for duration of colds



3) Severity of colds (standardized metric)

Two studies were included for this outcome (McEhlaney 2011 and Predy 2005). As per Figure 4), the severity of colds was lower, but did not achieve statistical significance for the COLD-FX® group (p=0.10).

Figure 4: Weighted Mean Difference Forest Plot of severity of cold



Conclusion:

In summary, these results support the effectiveness of COLD-FX® for preventing colds. There is insufficient evidence of a reduction in severity or duration of colds.

Conflicts of Interest:

The author declares no conflicts of interest.