Indication	Flu-type upper respiratory tract infection (treatment)
Level of evidence	III
Therapeutic benefit	Undetermined

Bibliographic reference

Braunig B, Dorn M, Knick E (1992). *Echinacea purpurea* radix for strengthening the immune response in flu-like infections. *Zeitschrift fur Phyto-therapie* 13 (1): 7-13.

Trial design

Parallel. Three treatment groups: two doses *E. purpurea* root extract and placebo.

Study duration Dose Route of administration	8-10 days 90 drops extract (2 droppersful, 450 mg root) or 180 drops extract (4 droppers- ful, 900 mg root) daily Oral
Randomized	Yes
Randomization adequate	No
Blinding	Double-blind
Blinding adequate	No
Placebo	Yes
Drug comparison	No
Site description	General practice
No. of subjects enrolled	180
No. of subjects completed	180
Sex	Male and female
Age	18-60 years

Inclusion criteria

Patients between 18 and 60 years old with flu-type infections.

Exclusion criteria

Patients who had been ill for more than three days from a flu-like infection; not readily cooperative; with additional infections, for instance, of the urological tract; those under treatment with antihistamines, antibiotics, and other relevant medications that influenced the disease profile; those who suffered other autoimmune diseases or immunologically relevant chronic diseases; patients who showed secondary infections such as bronchitis, pneumonia, pleuritis, and septic infections; bacterial illnesses such as pneumoconiosis and fungal infections; pussy angina tonsilleris; a sublingually measured fever of more than 40.5°C; or other serious illnesses.

348 HANDBOOK OF CLINICALLY TESTED HERBAL REMEDIES

allow for replication. Repeated measures would demand a different statistical approach. (1, 0)

Product Profile: Echinacea Plus®

Manufacturer U.S. distributor	Traditional Medicinals, Inc. Traditional Medicinals, Inc.
Formula botanicals	<i>Echinacea purpurea</i> (herb) <i>E. angustifolia</i> (herb) Water-soluble dry extract of <i>E. purpurea</i> (root; ratio 6:1), lemongrass (leaf), spearmint (leaf)
Quantity	Equivalent
Processing	See Formula botanicals
Standardization	Minimum 20 mg phenolic compounds (cichoric acid, chlorogenic acid, echinacoside) per one tea bag, as determined by HPLC
Formulation	Tea bag

Recommended dose: Three cups or more daily as needed. Pour 8 oz of boiling water over one tea bag and steep, covered, for 10 to 15 minutes.

DSHEA structure/function: Supports the immune system. Induces interferon production if needed by the body.

Cautions: The product should not be used during pregnancy and lactation without medical advice from a practitioner trained in medical herbalism.

Source(s) of information: Product package (Traditional Medicinals ©1999); Echinacea Plus® Herbal Dietary Supplement Technical Paper (©1998).

Clinical Study: Echinacea Plus®

Extract name Manufacturer	None given Traditional Medicinals, Inc.
Indication	Common cold/flu (treatment)
Level of evidence	II
Therapeutic benefit	Yes

362 HANDBOOK OF CLINICALLY TESTED HERBAL REMEDIES

Efamol Marine is supplied in capsules containing 430 mg EPO plus 107 mg marine fish oil (17 mg eicosapentaenoic acid [EPA], 11 mg docosahexaenoic acid [DHA]). Efamol Marine is manufactured in the United Kingdom by Scotia Pharmaceuticals Ltd. and is not available in the United States.

Efamast capsules, which contain 500 mg EPO, are manufactured by Searle in the United Kingdom. Efamast is not sold in the United States.

One trial used a generic product containing 0.6 ml EPO per capsule.

SUMMARY OF REVIEWED CLINICAL STUDIES

Essential fatty acids, including linoleic acid found in evening primrose oil, cannot be manufactured in the human body, and their supply is dependent on adequate dietary intake. Inadequate intake or compromised conversion to active metabolites can result in symptoms such as hair loss, eczema, disorders in connective tissue, poor wound healing, poor immune and reproductive function, and degeneration of organs, including the liver and kidney (Chen, 1999).

Trials using evening primrose oil preparations have been conducted on subjects with eczema, arthritis, attention-deficit hyperactivity disorder (ADHD, in children), diabetic neuropathy, premenstrual syndrome (PMS), benign fibroadenomas in the breast, and obesity. The majority of trials have focused upon atopic eczema, in which there appears to be a trend toward efficacy. EPO may also help ameliorate the uremic skin symptoms of those undergoing dialysis. In addition, EPO may improve mild diabetic neuropathy. No evidence indicates that it has any effect on ADHD in children, improves symptoms of arthritis or PMS, reduces benign fibroadenomas in the breasts, or helps obese women lose weight.

Atopic eczema or atopic dermatitis is a type of dermatitis in which an inflammation of the skin develops in persons subject to allergic reactions. It is associated with itching, redness, swelling, and blisters that may be weeping and progress to crusted, scaly, and thickened skin. The skin rash can be widespread or limited to a few areas. In teens and young adults, the patches typically occur on the hands and feet (American Academy of Dermatology, 1995).

374 HANDBOOK OF CLINICALLY TESTED HERBAL REMEDIES

cream and topical steroids used by patients during the study (as rescue medication) was also recorded.

Results

Patients in the evening primrose oil group consumed significantly less topical steroids over the course of 12 weeks (60 g versus 200 g, p < .05). A statistically significant improvement was observed in overall severity and grade of inflammation (p < .001), a significant reduction in surface area involved, as well as in dryness and itching (p < .01). Patients in the placebo group also showed a significant reduction in inflammation (p < .05). However, in every clinical parameter, the degree of improvement was significantly greater in the EPO group than in the placebo group. The level of DGLA increased significantly in the EPO group.

Side effects

No side effects were observed in the study.

Authors' comments

Although the patients were allocated to the two groups at random, the mean initial status of the eczema was somewhat worse in the EPO group than in the placebo group, which made it difficult to estimate the real effect of EPO. However, significantly greater improvement in every parameter in the EPO group, and the fact that the patients in the placebo group needed about three times as much topical steroids as did those in the EPO group, suggest that EPO was superior to placebo.

Reviewer's comments

The study was well designed and conducted, but the results were weakened by the small sample size. (5, 4)

Clinical Study: Efamol®

Extract name	N/A
Manufacturer	Efamol Ltd., UK
Indication	Uremic skin symptoms in hemodialysis patients
Level of evidence	ll
Therapeutic benefit	Yes

Bibliographic reference

Yoshimoto-Furuie K, Yoshimoto K, Tanaka T, Saima S, Kikuchi Y, Shay J, Horrobin D, Echizen H (1999). Effects of oral supplementation with evening