Bioxyne
An Australian Probiotic Company

# REVIEW

**Published clinical studies show that L. fermentum VRI-003 (PCC®) can boost the immune system of adults and infants.** Peter French PhD, Executive Director, Bioxyne Limited

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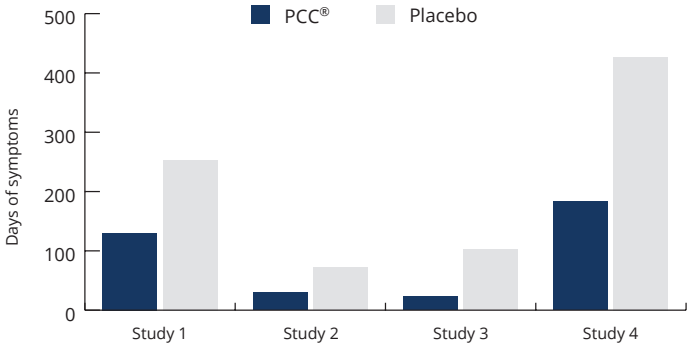
Lactobacillus fermentum VRI-003 (PCC®) is a patented probiotic[1] strain owned by Australian probiotic company Bioxyne Limited. PCC® was isolated from a person with high natural resistance to intestinal tract infections, and has been shown in scientific studies to be:

- naturally resistant to stomach acids and bile salts, meaning that no enteric coating of the capsules is needed;
- able to bind to immune areas within the gastrointestinal tract;
- stable at room temperature, which means that refrigeration is not necessary.

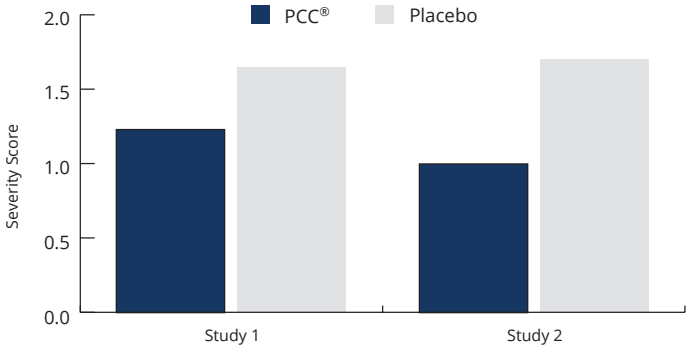
Five clinical studies (see references at the end of this document) provide evidence that PCC® may have the ability to boost the immune system of both adults and infants, and to reduce the duration and severity or respiratory tract infections. Three of the studies show that when taken orally, PCC® in capsules (1 billion CFU[2] or 10 billion CFU) daily can significantly reduce the duration of cold and flu symptoms (by more than half) in adults when taken before symptoms appear compared to placebo[3]:

**EFFECT OF L. FERMENTUM VRI-003 ON REDUCING THE NUMBER OF DAYS OF RESPIRATORY INFECTION SYMPTOMS IN ADULTS**




Two of these studies also showed that PCC® could also reduce the severity of cold and flu symptoms in elite male athletes:

**EFFECT OF L. FERMENTUM VRI-003 ON REDUCING THE SEVERITY* OF RESPIRATORY INFECTION SYMPTOMS IN ELITE MALE ATHLETES**

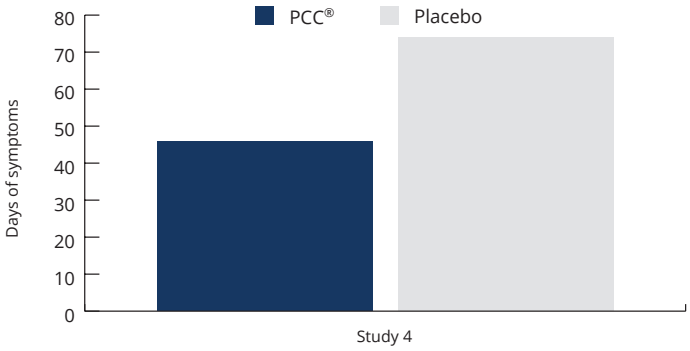



*Severity was rated on a 1–3 Likert scale where 1=mild, 2=moderate and 3=severe symptoms

(Note: Study 3 did not measure severity)

A fourth study reported that significantly fewer infants (aged 6 to 18 months) who were given PCC® (1 billion CFU) daily had lower respiratory tract infections compared to the placebo group (p=0.04):

**EFFECT OF L. FERMENTUM VRI-003 ON REDUCING THE INCIDENCE OF RESPIRATORY INFECTION SYMPTOMS IN INFANTS**

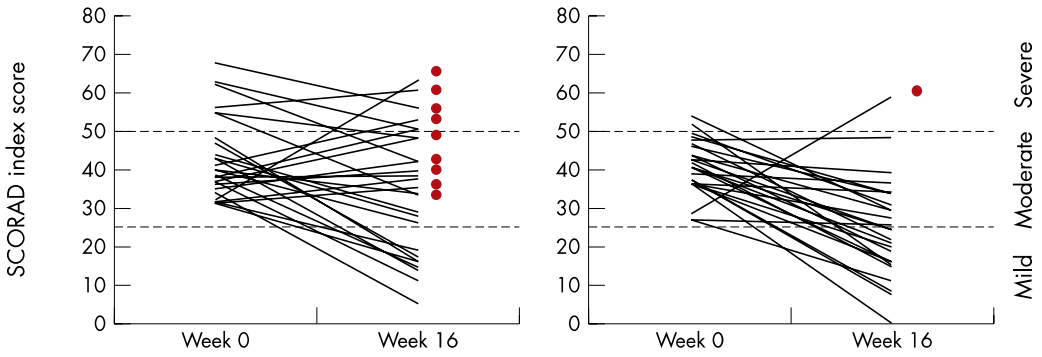



[1]**Probiotic**: live bacteria that, when administered in adequate amounts, provides a health benefit for the consumer. Usually a member of the Lactobacillus or Bifidobacteria families.

[2]**CFU**: Colony Forming Unit, a measure of the number of live bacteria in the dose.

[3]**Placebo**: a substance that has no therapeutic effect, used as a control in testing new medications. In the trials of PCC®, the placebo usually consisted of an inert substance, microcrystalline cellulose.

These infants were suffering symptoms of moderate to severe atopic dermatitis[4], and those who took PCC® daily had a significant improvement in their symptoms compared to placebo:




The above graphs from Study 4 show baseline and week 16 SCORAD index scores for each participant in the placebo and probiotic (PCC®) groups of infants with atopic dermatitis symptoms. The red dot (●) marks the participants whose symptoms worsened over the 16 weeks of the treatment.

Notably, the improvement in atopic dermatitis symptom severity with probiotic treatment was still evident 2 months after the treatment was ceased. In a follow up study (Study 5) the effect of PCC® on atopic dermatitis symptoms was shown to be associated with significant increases in the capacity for Th1 interferon gamma responses (a measure of activation of the innate immune response).

## CONCLUSION

PCC® is a probiotic that appears to be capable of modulating the mucosal immune system to reduce the severity and duration of respiratory infections, particularly in male athletes. PCC® also appears capable of modulating the innate immune system to reduce the inflammatory symptoms of atopic dermatitis in infants and to boost the immune response to a vaccine in adults. PCC® can produce these immune effects at daily doses (1 billion CFU) well below those of many commercial probiotic products many of which contain high numbers of non-specific and untested lactobacilli.

From these studies, it can be concluded that PCC® represents a potential powerful booster of the immune response for a variety of positive health benefits. More clinical studies are planned by Bioxyne to confirm these effects.

[4]**Atopic dermatitis (AD)** is a common chronic inflammatory skin disease that has increased in prevalence over the last half century. A growing body of evidence suggests that there are a variety of defects in the innate immune system that collectively affect the development and severity of AD.

## SUMMARY OF STUDIES CITED AND THEIR REFERENCES

**STUDY 1**
88 elite athletes.1 capsule (1 billion CFU PCC® or placebo) per day for 11 weeks.
West NP, Pyne DB, Cripps AW, Hopkins WG, Eskesen DC, Jairath A, Christophersen CT, Conlon MA, Fricker PA. Lactobacillus fermentum (PCC®) supplementation and gastrointestinal and respiratory-tract illness symptoms: a randomised control trial in athletes. Nutr J. 2011; 10:30. http://www.nutritionj.com/content/10/1/30

**STUDY 2**
20 male elite athletes. 6 capsules (12.6 billion CFU PCC® or placebo) per day for 16 weeks.
Cox AJ, Pyne DB, Saunders PU, Fricker PA. Oral administration of the probiotic Lactobacillus fermentum VRI-003 and mucosal immunity in endurance athletes. Br J Sports Med 2010; 44(4): 222-6.

**STUDY 3**
44 healthy adults vaccinated with the flu vaccine. 1 capsule (1 billion CFU PCC® or placebo) per day for 6 weeks.
French PW, Penny R. Use of probiotic bacteria as an adjuvant for an influenza vaccine. Int J Probiotics Prebiotics 2009; 4:175-80.

**STUDY 4**
56 children aged 6–18 months with moderate or severe atopic dermatitis. 1 billion CFU PCC® or placebo twice daily, administered as a powder sprinkled on food.
Weston S, Halbert A, Richmond P, Prescott SL. Effects of probiotics on atopic dermatitis: a randomised controlled trial. Arch Dis Child 2005; 90:892-7.

**STUDY 5**
Scientific analysis of blood samples from patients in Study 4.
Prescott SL, Dunstan JA, Hale J, Breckler L, Lehmann H, Weston S, Richmond P. Clinical effects of probiotics are associated with increased interferon-g responses in very young children with atopic dermatitis. Clin Exp Allergy 2005; 35:1557-64.