A multi-strain probiotic in the management of chronic and episodic migraine headaches: a randomised double-blind, placebo-controlled trial

Question:

Is the multi-strain probiotic more effective than placebo at reducing frequency and severity of both chronic and episodic migraines?

Methods:

Chronic migraine (CM) = characterised by 15 or more headache days per month.

Episodic migraine (EM) = characterised by those with migraine who have 0 to 14 headache days per month.

100 patients suffering from CM (n=50) or EM (n=50), or as defined by International Headache Classification ICHD III criteria, were recruited to receive either the probiotic (14 bacteria strains; 4 billion CFU per day) or placebo capsules for 8 weeks (see flow chart).

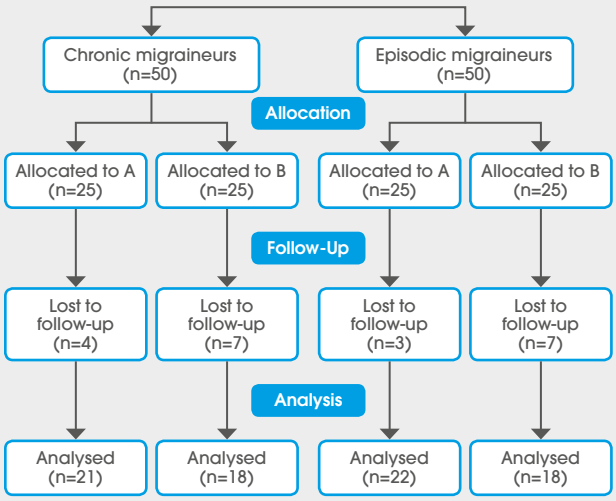


Fig 1. Flow chart of participants.
A = Probiotic group; B = Placebo group.

Results:

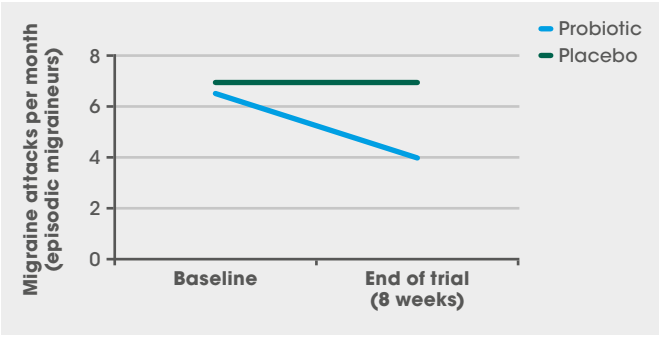
Chronic migraine:

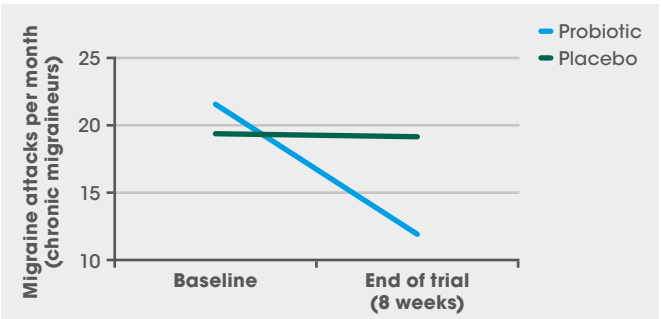
- In the probiotic group, 21/25 individuals completed the trial, whilst in the placebo group, 18/25 completed the trial
- By end of trial, mean frequency of attacks in probiotic group had fallen by 45% (~22 attacks per month → ~12 attacks per month), significantly better than the fall of 1% in the placebo group (P<0.001)

Visual Analogue Scale (VAS)-assessed migraine intensity significantly improved over the course of trial in the probiotic group but not in the placebo group (31% reduction vs 2% reduction; P<0.001).

Episodic migraine:

- In the probiotic group, 22/25 individuals completed the trial, whilst in the placebo group, 18/25 completed the trial
- By end of trial, the mean frequency of attacks significantly reduced in the probiotic group compare with placebo group (40% reduction from baseline vs <1% change; P<0.001)
- Migraine intensity measured by visual analogue scale (VAS) was also significantly improved with probiotics compared with placebo (29% reduction vs 2% increase; P<0.001)
- Migraine disability assessment score (MIDAS) by end of trial was significantly lower in probiotic group compared with placebo (~30% reduction vs ~7% increase; P<0.001)





Conclusion:

The multi-strain probiotic achieved a significant reduction in the frequency of headaches, and migraine symptom severity in both groups.

Martami, F., Togha, M., Seifishahpar, M *et al.* The effects of a multispecies probiotic supplement on inflammatory markers and episodic and chronic migraine characteristics: A randomized double-blind controlled trial. *Cephalalgia*. Jan 2019.

Probiotic Supplement used = Bio-Kult Advanced (Ingredients - Bulking agent: microcrystalline cellulose, *Bacillus subtilis* PXN® 21™, *Bifidobacterium bifidum* PXN® 23™, *Bifidobacterium breve* PXN® 25™, *Bifidobacterium infantis* PXN® 27™, *Bifidobacterium longum* PXN® 30™, *Lactobacillus acidophilus* PXN® 35™, *Lactobacillus delbrueckii* ssp. *bulgaricus* PXN® 39™, *Lactobacillus casei* PXN® 37™, *Lactobacillus plantarum* PXN® 47™, *Lactobacillus rhamnosus* PXN® 54™, *Lactobacillus helveticus* PXN® 45™, *Lactobacillus salivarius* PXN® 57™, *Lactococcus lactis* ssp. *lactis* PXN® 63™, *Streptococcus thermophilus* PXN® 66™, (milk, soya), vegetable capsule (hydroxypropyl methylcellulose).)

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Research Study

THE BACKGROUND:

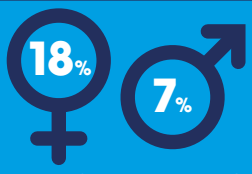
How common is migraine?

Migraine headaches affect 14% of the population

~6 million
people affected in the UK

>190,000
migraine attacks each day.

More common in females than males



What is the impact of migraines?

Migraine is the leading cause of disability among all neurological disorders

More than 50% of migraine patients are unhappy with their current treatment

25 million
work/school days lost each year

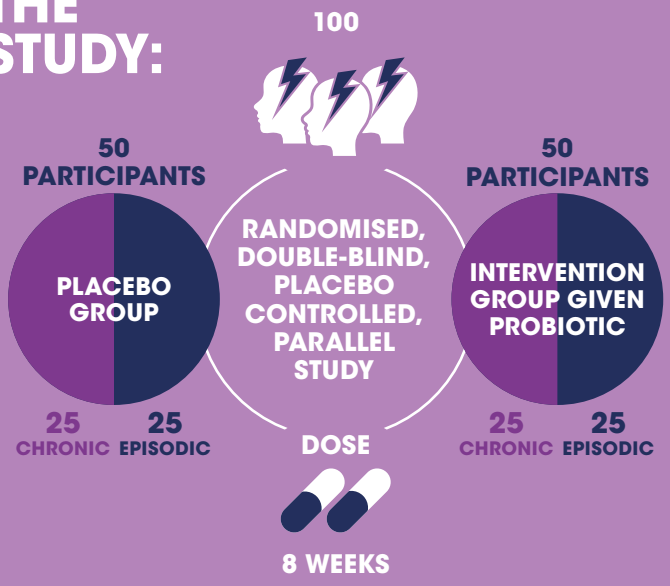
GP CONSULTATIONS | NEUROLOGY CONSULTATIONS

In the UK, 3% of GP consultations and 30% of neurology consultations are for headache, with migraine the most common diagnosis

The financial burden of migraine on the UK economy is conservatively estimated at almost

£3.5 billion
per year.

THE STUDY:



THE RESULTS:

Chronic Migraine: No. of attacks per month – Intervention Group

Episodic Migraine: No. of attacks per month – Intervention Group

No change in placebo group!

Mean frequency of headaches

Time	Baseline	8 weeks
CM - probiotic	22	12 (Decreased by ~10 per month)
CM – placebo	19	19 (No change)
EM - probiotic	7	4 (Decreased by ~3 per month)
EM - placebo	7	7 (No change)

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