



AxisBiotix-Ps™ BRIGHT Consumer Study Report

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1. Abstract

Psoriasis is a chronic inflammatory skin disease that impacts many millions of people worldwide and has a substantial effect on quality of life. There is increasing evidence that the gut microbiome can impact skin health and influence such diseases. AxisBiotix-Ps™ is a food supplement made up of a bespoke blend of bacteria, which is intended to modulate the immune system by harnessing the gut-skin axis to address problems associated with sensitive skin conditions, such as psoriasis.

This report analyses data from the AxisBiotix-Ps™ BRIGHT consumer study to better understand how people with sensitive skin conditions, particularly those with psoriasis, experience AxisBiotix-Ps™. Over two thirds of participants with psoriasis that completed the study and took AxisBiotix-Ps™ for 56 days saw an improvement in skin health (i.e. less irritability, itchiness, flakiness and/or redness), and of these, the majority also experienced an improvement in quality of life.

2. Study background

Psoriasis is a chronic inflammatory skin disease which currently affects between 2-3% of the UK population (c.1.8 million people) and up to 125 million people worldwide [source: www.psoriasis.org]. The most common symptoms include red patches of skin covered with scales, very dry, inflamed skin, and itching, but for some patients it also impacts their hair and nails. Psoriasis can seriously impact quality of life due to sleep disturbances and embarrassment in social situations. Current treatments for psoriasis include emollients, topical steroids, phototherapy, or even systemic therapies for those whose disease is not responding well to topical therapies.

2.1. Bacteria in the gut

Although the most obvious manifestations of psoriasis are on the skin, the disease also involves the immune system. Bacteria in the gut are proven to be very important for the functioning of the immune system and some of them are known to be able to reduce inflammation. This led to the hypothesis that a bespoke blend of bacteria could be used in supporting skin health for psoriasis patients.

3. Objective

The AxisBiotix-Ps™ BRIGHT Consumer Study was designed to assess consumer attitudes and experience of the AxisBiotix-Ps™ bacterial blend, taken as a food supplement, to evaluate how it impacts quality of life and skin health. This report focuses on the results in participants with psoriasis.

4. Study design

4.1. Admission to study

The inclusion criteria for the study were that participants should: have a sensitive skin condition, be aged 18 or over and live in the UK at the time of the study.

Potential participants were asked to complete a short pre-qualification questionnaire on the AxisBiotix website to assess eligibility. This included asking whether they had sensitive skin and/or any of five specific skin conditions.

The eligible participants were grouped into the following cohorts:

- Psoriasis
- Psoriasis and other skin conditions
- Eczema
- Contact dermatitis
- Rosacea
- Acne

The final participants were then selected from those who were eligible in order to obtain, where possible: equal representation of females and males; equal representation of participants above and below 40 years old; and proportional representation of ethnicities as per the UK Census 2011.

After registering interest and being selected for the study, the final participants were informed of any details and terms for participation via the website.

4.2. Study procedure

Following selection, participants downloaded the 'AxisBiotix Feedback' mobile app, which they would use to provide feedback on their experience of the product.

A supply of AxisBiotix-Ps™ was mailed to each participant and they were instructed to take the product every day for 56 days. During these 56 days, participants received daily reminders via the app to take the supplement and to complete the questionnaires.

4.3. Assessment procedure

Participants were asked to complete a short weekly questionnaire on 'Skin Health & Lifestyle' for a period of 56 days via the mobile app. As part of these questionnaires, the app also enabled participants to take photographs of their skin. These photographs were taken by participants on their mobile devices in their home environments, not under controlled conditions.

This report summarises the results from this series of 'Skin Health & Lifestyle' questionnaires.

5. Results

5.1. Demographic data and drop-outs

5.1.1. Participants enrolled

267 participants were enrolled in the study. Of these, 177 reported that they had psoriasis, 42 reported that they had psoriasis and some other skin condition, and 48 reported that they had a skin condition different from psoriasis, such as eczema, acne, rosacea or contact dermatitis. This report focuses on the results obtained for the participants with psoriasis only.

5.1.2. Drop-outs

Of the 177 participants with psoriasis, 142 started the study and completed the Day 7 questionnaire. 91 of these 142 participants went on to complete the study and respond to the last questionnaire. Table 1 details the demographics of these 91 participants.

Four study participants experienced symptoms after taking AxisBiotix-Ps™, including headaches, nausea and stomach ache. These reactions are well documented in other studies of probiotic products so were not unexpected or unusual.

Table 1. Demographics of participants with psoriasis that completed Day 56 questionnaire.

Skin Condition	Gender	Age	Ethnicity	Total
Psoriasis	43 Females	9 Aged <40	6 White	
			2 Asian	
			1 Other	
		34 Aged >40	29 White	
		2 Asian		
		3 Other		
	48 Males	11 Aged <40	9 White	
			1 Asian	
		1 Other		
37 Aged >40		33 White		
	3 Asian			
	1 Other			
Total				91

5.2. Weekly questionnaire results

The weekly questionnaires on the BRIGHT Consumer Study, included two subsets of questions: Set 1 – Skin Health Questions, and Set 2 – Lifestyle Questions.

The questions considered most significant for participants with a skin condition such as psoriasis were:

From set 1 – Skin Health Questions

- a) Since you started taking AxisBiotix-Ps™, how has your skin felt in respect to the following:
 1. My skin feels less irritable
 2. My skin feels less itchy
 3. My skin has fewer flaky patches
 4. My skin feels less red

From set 2 – Lifestyle Questions

- b) Since you started taking AxisBiotix-Ps™, has the condition of your skin affected the following:
 1. I have more energy
 2. I sleep better
 3. My mood has improved
- c) Since you started taking AxisBiotix-Ps™, do you feel healthier?

Participants were given the choice of four possible answers to each question: ‘No change’, ‘A little’, ‘A lot’ and ‘Very much’. This report looks to compare the results from participants that did not experience any change in their skin health and lifestyle (‘No Change’) and participants that reported an improvement in their skin health and lifestyle (‘A little’, ‘A lot’ or ‘Very much’).

5.2.1. Day 56 analysis

Figure 1 shows the overall averaged results across all four aspects of skin health (including irritability, itchiness, redness and flakiness). Of the 91 participants with psoriasis that completed the study, an average of 72% reported an improvement across these four skin health areas on Day 56.

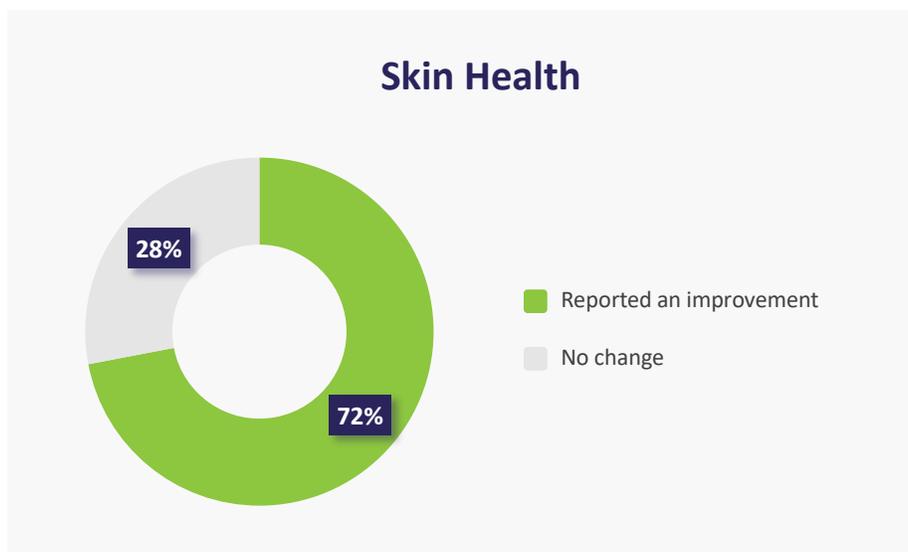


Figure 1. Average percentage of responses across the four areas of skin health (including irritability, itchiness, redness and flakiness) on Day 56. Number of participants: 91

Breaking this down to look specifically at each aspect of skin health, as shown in Figure 2, 73% of the 91 participants reported that their skin was less irritable, 76% that their skin was less itchy, 75% that their skin was less red, and 65% reported fewer flaky patches on their skin after taking AxisBiotix-Ps™ for 56 days.

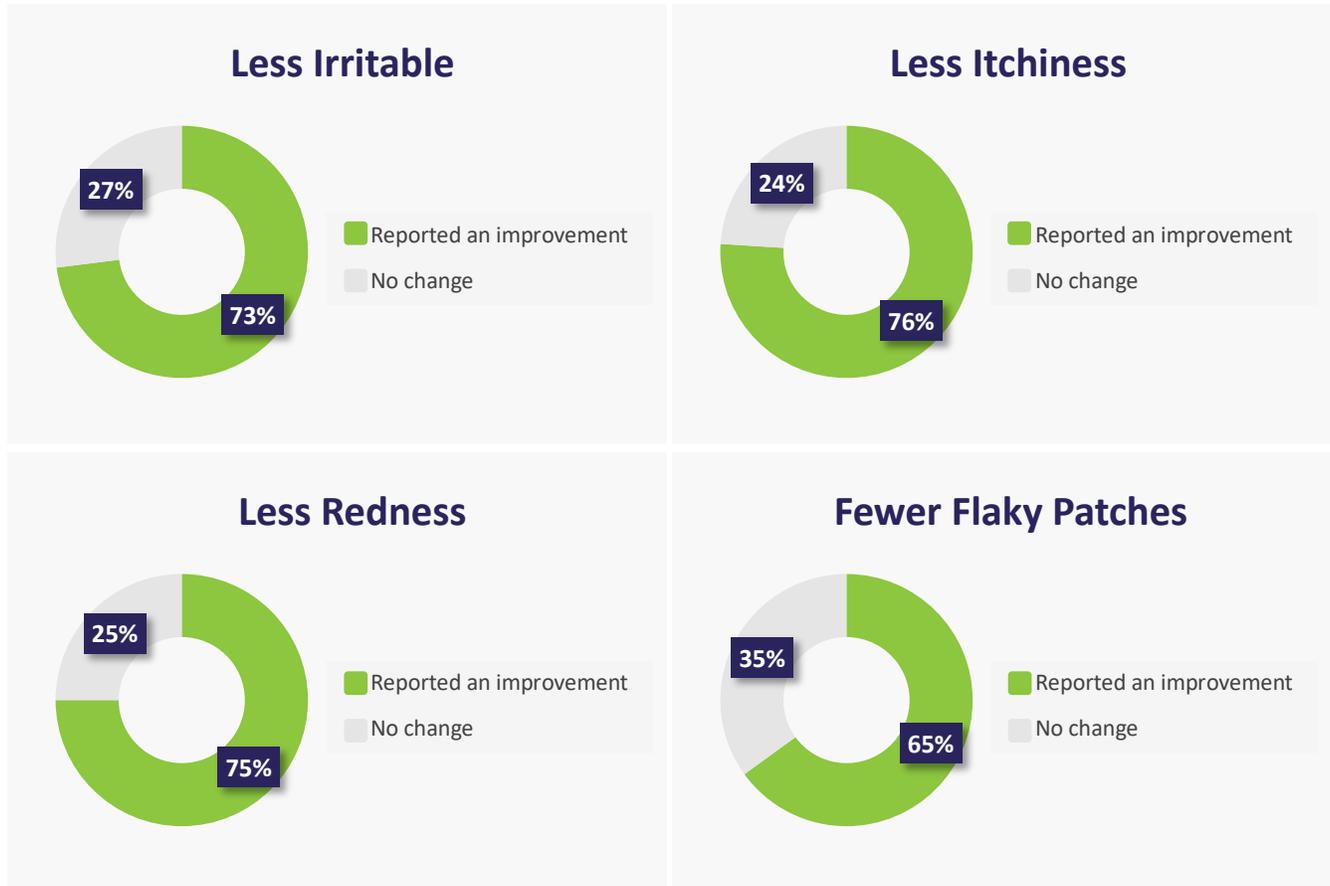


Figure 2. Participant responses on change in irritability, itchiness, flakiness and redness of skin after taking AxisBiotix-Ps for 56 days ('No change' or Reported an Improvement ('A little', 'A lot' or 'Very much')). Number of participants: 91

From the participants that reported a positive change to their skin health (itchiness, irritability, redness and/or flakiness) on Day 56 (an average of 66 participants), the majority also experienced an improvement in quality of life (energy levels, sleep, and mood) (Figure 3). For example, of the 73% of participants that reported their skin was less irritable on Day 56, 64% felt more energetic, 65% slept better and 67% had a better mood. Similar improvements in wellbeing were also observed in participants reporting reductions in itchiness, redness and flaking (Figure 3).

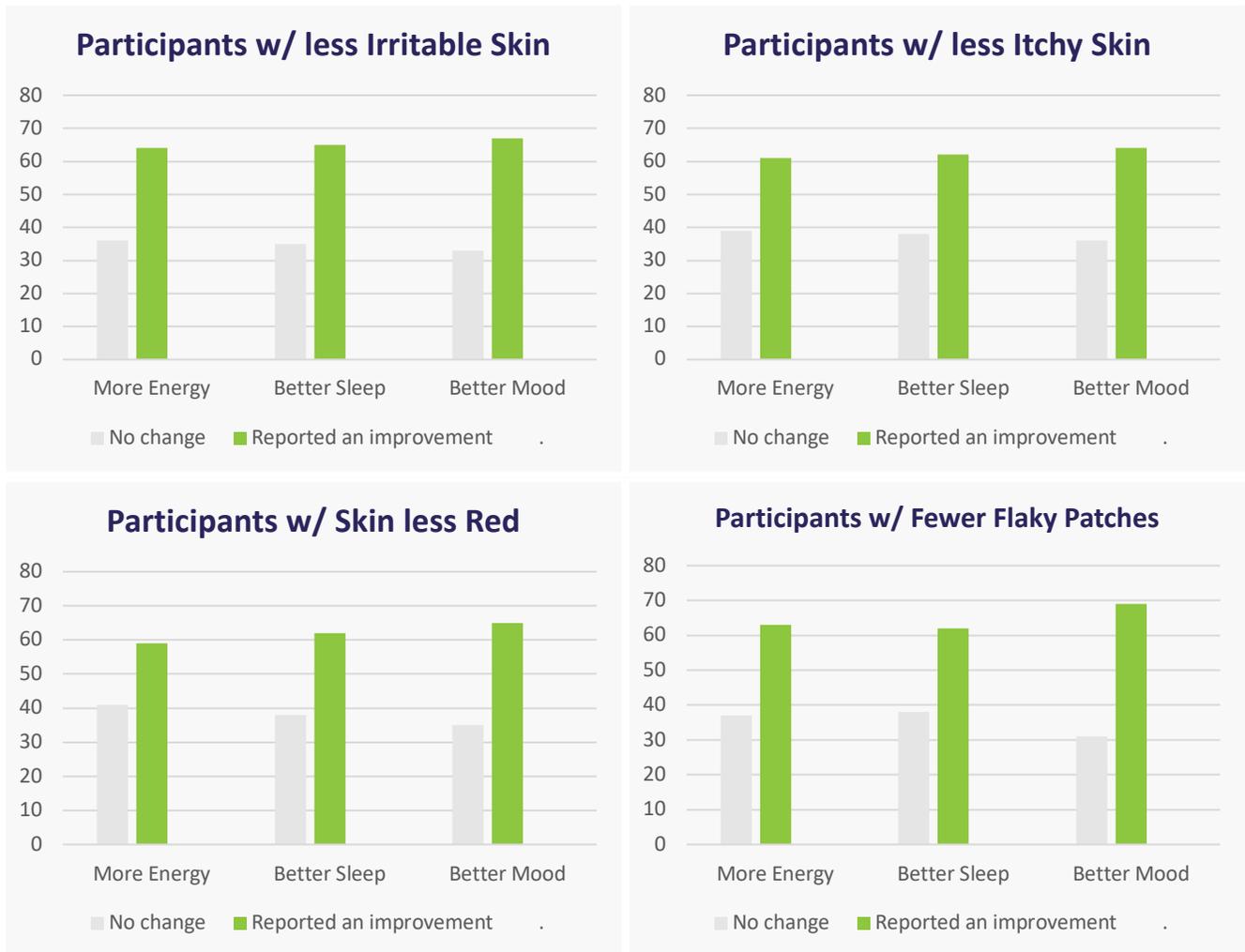


Figure 3. Percentage of participants that reported 'No change' or an improvement ('A little', 'A lot' or 'Very Much') in their lifestyle, who also reported an improvement in their skin irritability, itchiness, flakiness and/or redness.

Additionally, 59% of the 91 participants that completed the study said they felt healthier after taking AxisBiotix-Ps™ for 56 days (Figure 4).

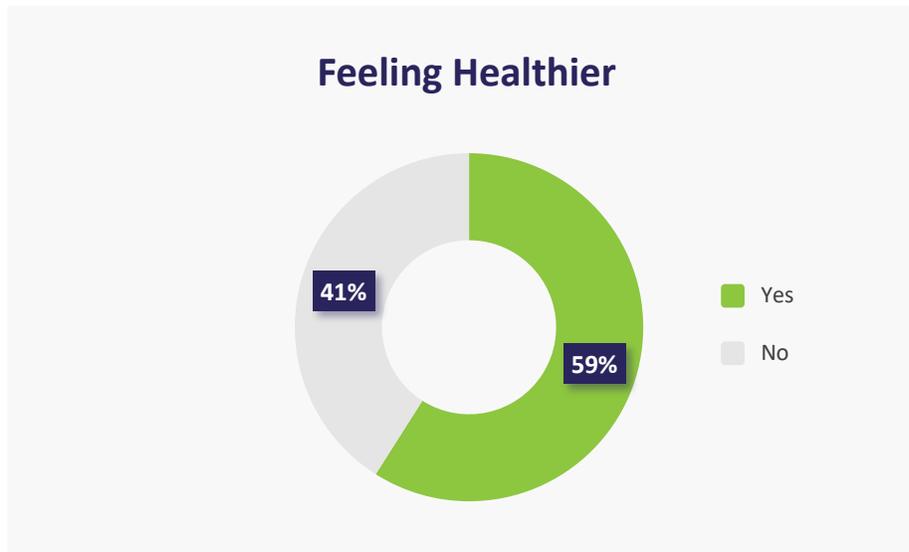


Figure 4. Percentage of participants that felt healthier vs. did not feel healthier after taking AxisBiotix-Ps™ for 56 days. Number of participants: 91

6. Conclusions

The AxisBiotix-Ps™ BRIGHT consumer study has contributed to our understanding of how people with a skin condition such as psoriasis use and experience AxisBiotix-Ps™. The data suggests that:

- 1) On average 72% of participants that completed the study experienced an improvement in their skin health (i.e. skin less irritable, less itchy, less flaky and less red).
- 2) There is a correlation between an improvement in skin health, and an improvement in quality of life after taking AxisBiotix-Ps™ for 56 days.