



AxisBiotix™ Acne Food Supplement Consumer Study Report

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1. Abstract

Acne is a common skin condition and one of the top 10 most prevalent diseases worldwide. There is increasing evidence that the gut microbiome can impact skin health and influence such diseases. AxisBiotix™ 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.

This report analyses data from the AxisBiotix™ Acne food supplement consumer study to better understand how people with skin conditions experience AxisBiotix™. The feedback from study participants was incredibly positive, with 89% confident at the end of the study that they would both continue to use AxisBiotix™ and recommend the supplement to others.

2. Study background

Up to 85% of people will suffer from acne at some point in their life and sufferers tend to be keen to alleviate their symptoms. The global acne market is worth \$9.4billion with CAGR of 4.8% (Fortune Business Insights 2019). In the UK alone, the market is worth c. £250m in 2022 and is projected to reach c.£300m in 2030, with c.34% of adults in the UK experiencing acne at some time in their lives. Acne is the most common skin condition and one of the top 10 most prevalent diseases worldwide.

Acne can range from mild to severe and typically affects teenagers and young adults but anyone can be affected. Treatment of severe acne often requires topical steroid creams which can lead to undesirable side effects, including skin dryness, irritation, and rashes. Alternative treatments include oral medications where side effects can be more severe e.g. depression or suicidal thoughts.

3. Study objective

The AxisBiotix™ Acne food supplement consumer study is an 8-week trial which recruited volunteers to assess the efficacy of AxisBiotix™, a food supplement made up of a bespoke blend of bacteria, on their acne.

4. Study design

The trial began in January 2024.

Following screening and acceptance to the trial, participants were asked to take AxisBiotix™ every day for 8 weeks and to provide feedback on their experience on a weekly basis via a bespoke app.

The study, comprising 91 people, followed the same methodology as the AxisBiotix-Ps™ study. The supplement containing the lead formulation was supplied to participants in powder-form.

At the end of the 8 weeks, participants were also asked to complete an exit survey, built using Google Forms and accessed via the web.

Every week, Datitude was used to download the data from the app into a data warehouse. The data was used to build a bespoke Tableau workbook to analyse the results.

This short report summarises the results from the weekly app data and the exit survey as at the date of data cutoff, 21 May 2024.

5. Results

5.1. Enrolment and drop-outs

At week 1, the study included 98 participants, with statisticians generally agreeing that a population of 100 is statistically significant.

At the point of data cutoff, 85 participants had reported every week until week 8 – an 87% completion rate.

91 participants (93%) completed the exit survey, i.e. more participants completed the exit survey than all of the 8 weeks of feedback.

5.2. Weekly monitoring

5.2.1. Data gathered

The weekly questionnaires conducted via the bespoke app included two subsets of questions: set 1 – the rating questions, and set 2 – questions on the participants' usage experience.

For set 1, participants were asked to rate their skin each week against four criteria on a scale of 0 to 10:

1. How do you rate the severity of your spots?
Mild – severe
2. How concerned are you about the effect your spots have on your appearance?
Not concerned – extremely concerned
3. How painful are your spots?
Not – extremely
4. Do you worry about going out in public because of your spots?
Never – always

For set 2, participants were asked five questions about their usage experience:

1. Have you forgotten to take the supplement on any days in the past week?
2. How easy did you find the supplement was to prepare?
3. Did you use the supplement with water, milk or yoghurt?
4. How did you find the taste of the supplement on a scale of 1 (disliked) to 5 (liked)?
5. Did you take the supplement in the morning or the evening?

5.2.2. Rating questions

Figure 1 shows an overview of the results from the rating questions. For each of the four criteria we have calculated the mean score given by our study participants across the eight weeks.

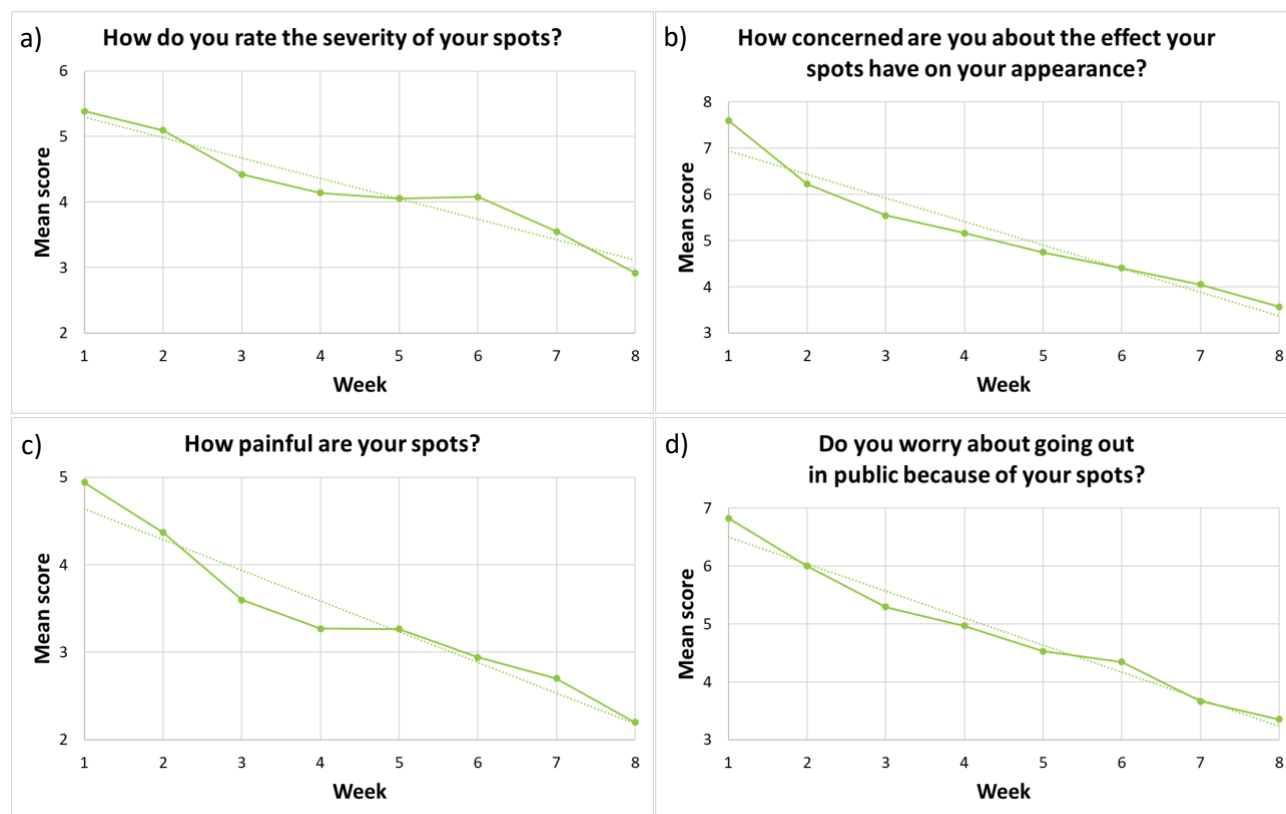


Figure 1: Mean average participant rating of a) spot severity, b) concern, c) pain, and d) worry, across the 8-week study assessing the efficacy of AxisBiotix™

With regards to spot severity, at week 1, 83% of participants rated their spots 4 or worse, using the scale 0 (best) to 10 (worst), but by week 8 this had decreased to 33%. At week 1, the most common score was 5 (31% of participants) and results ranged between 2 and 10. By week 8, the most common score had improved to 1 (21% of participants), with results ranging from 0 to 7. Notably, by week 8 no participants rated their spots worse than 7.

In addition, we recorded the difference in how participants rated the severity of their spots in week 8 compared to week 1, as shown in the histogram in Figure 2. Each bar on the chart represents a single participant and their rating change, which range from an improvement of +8 (blue) at the top, to a deterioration of -5 (amber) at the bottom. Overall, 69 participants (81%) reported an improvement in their spots, 8 (9%) reported no change, and 8 (9%) reported a worsening.

The concern felt by participants that their spots impacted their appearance was significant. At week 1, the most common score was 10 (24% of participants). However, this had dramatically improved by week 8, when the most common score was 2 (20% of participants). At week 1, 98% of participants rated their concern 4 or higher, using the scale 0 (no concern) to 10 (extremely concerned), but by week 8 this had decreased to 41%.

We also saw a reported reduction in pain from our participants' spots across the course of the study. At week 1, 70% of participants rated their pain as 4 or worse, using the scale 0 (not painful) to 10 (extremely painful); at week 8, this had decreased to 22%. At week 1, the most common score was 5 (30% of participants), but by week 8 this had reduced to 0, no pain (27% of participants), with just 3 participants rating their pain at 8 or above.

The worry at going out in public due to their spots proved another significant issue for our trial participants. At week 1, the most common scores were 10 (always worried, 22% participants) and 5 (24% participants). This

dramatically improved by week 8, by which time the most common score was 1 (21% of participants). At week 1, 92% rated their worry as 4 or worse, using the scale 0 (never worry) to 10 (always worry), but by week 8 this had decreased to 38%.

It is noteworthy that the question around worry at going out in public is open to interpretation. Responses may not reflect how much participants currently worry and may instead reflect a theoretical response on how significantly they would worry if they had spots.

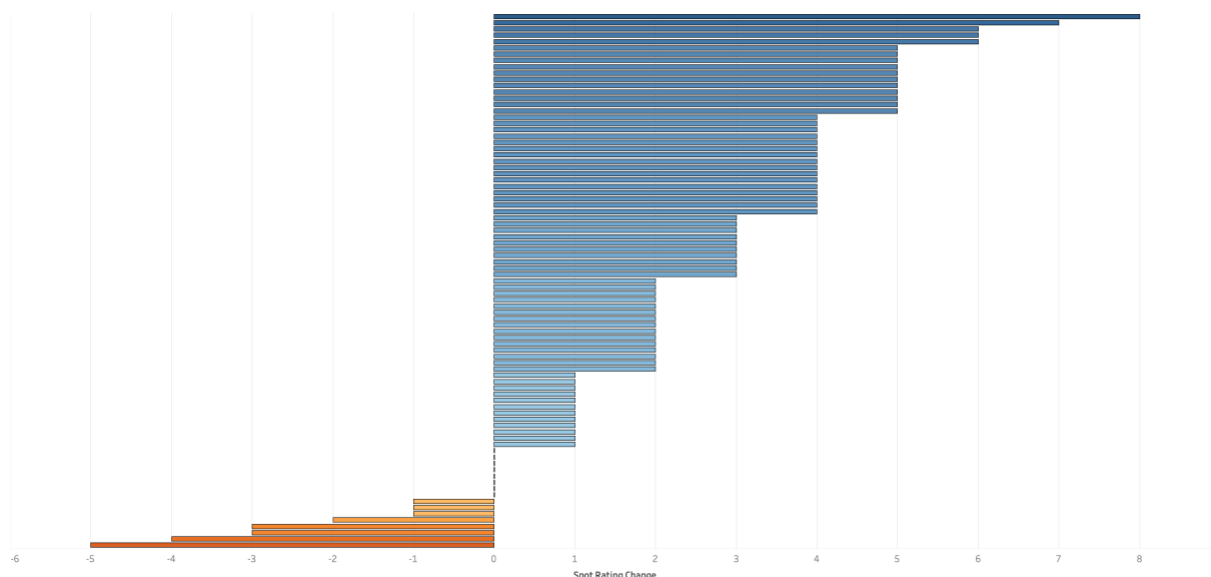


Figure 2: Change in participant rating of spot severity from week 1 to week 8 of study

5.2.3. Usage experience questions

Set 2 of the weekly questions pertained to the participants' usage experiences.

With regards to forgetting to take the supplement, the majority of participants succeeded in taking AxisBiotix™ every day. On average across the 8-week study, 75% of the participants did not forget to take the supplement on any days. An average of 17 % forgot one day in a week, 5% two days, and 2% three days or more days. There was no trend of improving or worsening adherence to the daily dose requirement as the study progressed.

Participants' responses to the other usage experience questions showed that:

- 57% of participants found AxisBiotix™ easy to prepare, scoring it 1 on a scale 1 (easy) to 5 (difficult)
- 80% prepared it with water, 12% with milk, and 7% with yoghurt
- 39% found the taste neutral, 35% disliked or strongly disliked it, and 25% liked or strongly liked it
- 79% took AxisBiotix™ in the morning and 21% in the evening

5.3. Exit questionnaire

5.3.1. Data gathered

At the end of the study, participants were asked to complete an exit questionnaire. This questionnaire asked participants to provide a final score against the four criteria monitored across the 8 weeks of the study – spot severity, concern about effect of spots on appearance, pain, and worry about going out in public. In addition, it asked participants to rate how their skin had changed over the course of the trial against six additional criteria,

and asked whether the participants would continue to use AxisBiotix™ and/or would recommend it to someone else.

5.3.2. Rating questions

Interestingly, we found some discrepancy between how our study participants scored their spot severity, concern about effect of spots on appearance, pain, and worry about going out in public, in the exit interview compared to at week 8 of the study. Figure 4 shows the results reported from the exit questionnaire compared to at week 8 in the app.

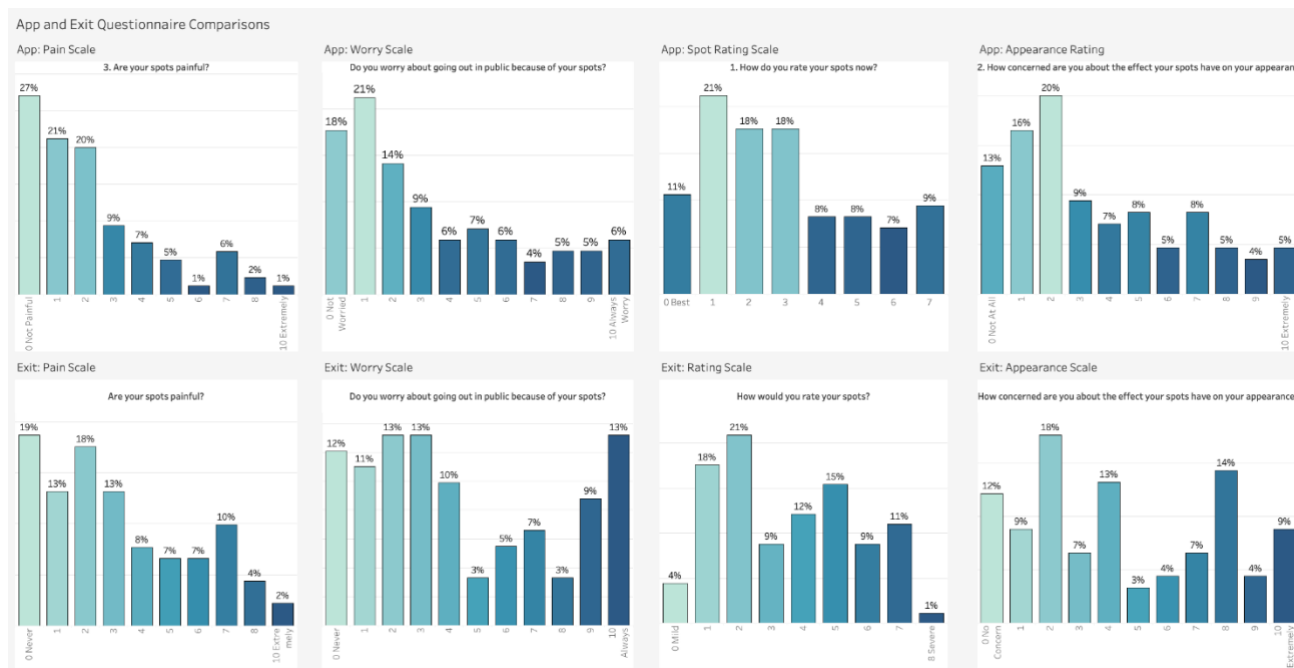


Figure 3: Participant ratings of pain, worry, spot severity, and concern about appearance at the end of the 8-week study

Overall, at the end of the 8-week study, using the app, 85% of participants scored their pain at 0-4, using the scale 0 (not painful) to 10 (extremely painful). This compared to 70% rating their pain 0-4 in the exit questionnaire. Similarly, 68% rated their worry at 0-4 in the app, compared to 59% in the exit questionnaire. 75% rated the severity of their spots at 0-4 in the app, compared to 64% in the exit questionnaire. And 66% rated their concern about their appearance at 0-4 in the app, compared to 58% in the exit questionnaire.

5.3.3. Continuation and recommendation

The feedback from a significant majority – 89% – of participants was that they would both continue to use and recommend AxisBiotix™ to others. Just 5% of participants fed back that they would neither continue to use nor recommend the supplement.

5.3.4. Skin change criteria

Figure 4 shows how the participants felt the 8-week course of AxisBiotix™ had impacted their skin, with regards to appearance, pain, and scarring, as well as their wellbeing, with regards to anxiety, impact on social life, and impact on activities, such as sport.

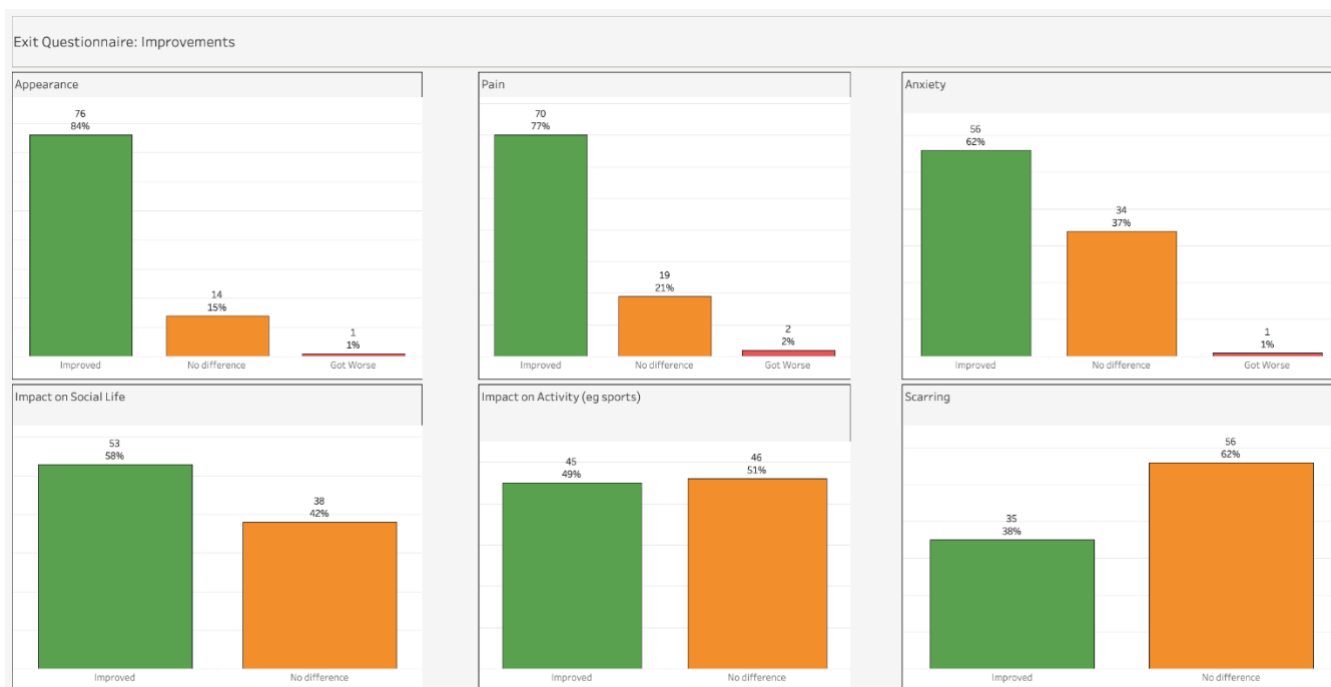


Figure 4: Participant feedback on the change in spot appearance, pain and scarring, and their anxiety, social life, and at the end of the 8-week study

The results were highly positive, with only four participants answering “got worse” across any of the six criteria. The most positive improvement was seen in appearance with 84% reporting improvement; followed by pain with 77%, anxiety with 62%, and then impact on social life with 58%. We were not surprised by the result that the majority of participants (62%) did not feel that the supplement made a difference to their scarring.

6. Conclusions

The AxisBiotix™ Acne food supplement consumer study has contributed to our understanding of how people with common skin conditions use and experience AxisBiotix™.

The feedback from study participants was very positive, with 89% confident at the end of the study that they would both continue to use AxisBiotix™ and recommend the supplement to others. This was based on a clear correlation between an improvement in skin health, and quality of life after taking AxisBiotix™ for 8 weeks.

Overall, 84% of participants reported that the appearance of their spots had improved, 77% that the pain caused by their spots had eased, 62% that the anxiety they felt due to their spots had improved, and 58% that the impact their spots had on their social life had improved.