

A SINGLE-BLIND, RANDOMISED HOME-USE STUDY, IN 50 HEALTHY MALE AND FEMALE VOLUNTEERS, WITH SELF-ASSESSED ANXIETY, TO EVALUATE THE EFFICACY OF ONE NUTRITIONAL SUPPLEMENT COMPARED TO PLACEBO, AS MEASURED BY SELF-PERCEPTION QUESTIONNAIRE (SPQ).

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A SINGLE-BLIND, RANDOMISED HOME-USE STUDY, IN 50 HEALTHY MALE AND FEMALE VOLUNTEERS, WITH SELF-ASSESSED ANXIETY, TO EVALUATE THE EFFICACY OF ONE NUTRITIONAL SUPPLEMENT COMPARED TO PLACEBO, AS MEASURED BY SELF-PERCEPTION QUESTIONNAIRE (SPQ).

PCR CORP REPORT NO: NUTUSE1M

I declare that the following report constitutes a true and faithful account of the procedures adopted and the results obtained in the performance of this study. The aspects of the study conducted by PCR Corp. were performed, where relevant, in accordance with the principles of Good Clinical Research Practice.

Barrie Drewitt
(Principal Investigator)


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Date ..13th December 2016.....

Jo Broyd
(Project Manager)


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Date ..13th December 2016.....

QUALITY ASSURANCE STATEMENT

This report has been audited and is considered to be an accurate description of the methods used and an accurate presentation of the data obtained during the conduct of the study.

Reece Statham
(Quality Assurance Manager)


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Date ..13th December 2016.....

CONTENTS

1	SUMMARY	4
2	KEY STUDY PERSONNEL AND RESPONSIBILITIES	5
3	INTRODUCTION AND OBJECTIVES	6
4	STUDY DESIGN	6
5	SELECTION OF SUBJECTS	6
6	TEST ARTICLES	7
7	STUDY PROCEDURE	7
8	STUDY ETHICS	8
9	RESULTS	9
	APPENDIX 1: SUBJECT CONSENT FORM	13
	APPENDIX 2: SUBJECT INFORMATION SHEET – NUTUSE1M	16
	APPENDIX 3: PRE-TREATMENT QUESTIONNAIRE	17
	APPENDIX 4: TEST ARTICLES INCI LISTINGS	19
	APPENDIX 5: RANDOMISATION	20
	APPENDIX 6: SUBJECT DIARY	21
	APPENDIX 7: SELF-PERCEPTION QUESTIONNAIRE	23
	APPENDIX 8: SELF-PERCEPTION QUESTIONNAIRE INDIVIDUAL RESPONSES – TEST SUPPLEMENT	25
	APPENDIX 9: SELF-PERCEPTION QUESTIONNAIRE INDIVIDUAL – PLACEBO	28

1 **SUMMARY**

Title:	A single-blind, randomised home-use study, in 50 healthy male and female volunteers, with self-assessed anxiety, to evaluate the efficacy of one nutritional supplement compared to placebo, as measured by Self-Perception Questionnaire (SPQ).
Study design:	Single blind, randomized home-use study.
Test Articles:	One active nutritional supplement and one placebo (Labelled): 1. Nutritional Supplement A 2. Nutritional Supplement B
Number of subjects:	Fifty (50)
Type of subjects:	Healthy male and female volunteers, aged over 18 years, with self-assessed anxiety.
Method:	Subjects attended the test centre at baseline (Day 1) to complete the informed consent form (ICF). Subjects were issued their supplement, diary and instructions. They were instructed on how to take their supplement, complete their diary over the next 30 Days, including the 2 Self-Perception Questionnaire (SPQ) questions daily, which are on their diary. At the end of the study (Day 30) subjects returned to the test centre to complete an online Self-Perception Questionnaire (SPQ).
Conclusion:	As can be seen from the data the product performed highly favourably under Clearcast guidelines, over the 30 day testing period shown by Top 2 responses (Strongly Agree + Agree) being >80% (regarded as highly favourable). The Sponsor's product also performed statistically significantly better than the Placebo product for all comparable questions. With 100% of subjects noticing an improvement in their level of anxiety and 68% of subjects feeling calmer after only 30 minutes.
Duration of study:	Study Started: w/c 5 th September 2016 Study Ended: w/e 7 th October 2016
Location:	PCR Corp. 8 Richmond Road Dukes Park Chelmsford Essex CM2 6UA United Kingdom

2 KEY STUDY PERSONNEL AND RESPONSIBILITIES

Key personnel	General responsibilities
<p>Principal Investigator (PI) Barrie Drewitt PCR Corp Princeton Forrestal Center 307 College Road East Princeton, NJ 08540</p> <p>Tel: 609-455-1112</p>	<p>The Principal Investigator (PI) will be responsible for ensuring sufficient resources are available to conduct the study according to Good Clinical Practice (GCP), for the study design, compiling the results and writing the clinical report.</p>
<p>Project Supervisor (PS) Andrew King PCR Corp 8 Richmond Road Dukes Park Chelmsford Essex CM2 6UA United Kingdom</p> <p>Tel: +44 (0) 1245 934050</p>	<p>The Project Supervisor (PS) will be responsible for the conduct of the study on a daily basis.</p>
<p>Project Manager (PM) Jo Broyd PCR Corp 8 Richmond Road Dukes Park Chelmsford Essex CM2 6UA United Kingdom</p> <p>Tel: +44 (0) 1245 934050</p>	<p>The Project Manager (PM) will be involved with the study design, compiling the results and writing the clinical report.</p>
<p>Project Co-ordinator (PC) Dan Watters Nutreance 401 Riversville Road Greenwich CT. 06831</p> <p>Tel: 1 (800) 749-7776 Email: support@nutreance.com</p>	<p>The Project Co-ordinator (PC) will be the primary point of contact on behalf of the Sponsor of this project and will represent the Sponsor (Nutreance) of this study.</p>

3 INTRODUCTION AND OBJECTIVES

The objective of this study was to evaluate the perceived efficacy of a nutritional supplement versus a placebo following continued home-use for four weeks via completion of a self-perception questionnaire (SPQ) at the end of the study. With the aim of supporting the following targeted claims proposed by sponsor:

X% of subjects noticed an improvement in their level of anxiety

X% of subjects felt calmer after only 30 minutes

Please note that it was the responsibility of the sponsor to determine the testing and study designs required for submission to entities such as the Home Shopping Network, QVC, etc.

4 STUDY DESIGN

Single-blind, randomised home-use study.

5 SELECTION OF SUBJECTS

5.1 Screening

A sufficient number of subjects were screened into the study to allow for fifty subjects to enter the active phase. Subjects satisfied the following inclusion and exclusion criteria, and the subjects accepted the prohibitions and restrictions and gave written informed consent (Appendix 1 & 2).

The suitability of potential subjects was confirmed before their acceptance onto the study by review of a study specific pre-treatment questionnaire (Appendix 3).

5.2 Inclusion criteria

- a) Healthy male and female volunteers, aged over 18 years of age, with self-assessed anxiety.
- b) Subjects have completed a written informed consent.

5.3 Exclusion criteria

- a) Subject is currently on prescription anti-anxiety medication or anti-depressants.
- b) Subject is pregnant, nursing, or planning to become pregnant;
- c) A current skin disease of any type (e.g. eczema, psoriasis) apart from mild facial acne.
- d) History of malignant disease.
- e) Significant past medical history of hepatic, renal, cardiac, pulmonary, digestive, haematological, neurological, locomotor or psychiatric disease.
- f) History of asthma requiring regular medication.
- g) Known sensitivity to the test article, similar materials or their constituents.
- h) Current participation in a clinical trial or follow-up.

5.4 Prohibitions and Requirements

- a) Subjects agree to use the trial product assigned as instructed, instead of their usual brand for the duration of the study.
- b) Subjects who are vegetarian and vegan to be made aware of the gelatin content in the placebo capsule.

6 TEST ARTICLES

To the best of the Sponsor's knowledge and based on the information available, PCR Corp considered the test article to be safe for use in man.

The following test article was supplied by the Sponsor labelled as follows:

1. Supplement A
2. Supplement B

The test articles and placebo were decanted into plain packaging plastic bags by PCR Corp. The Sponsor has provided ingredient listings for the test article (see Appendix 4).

It was the responsibility of the Sponsor to determine, for each batch of the test article, the identity, strength, purity, composition and other characteristics which appropriately define the test article, before its use in the study. The determination of its stability and documentation of methods of synthesis or derivation were also the Sponsor's responsibility.

It was the responsibility of the Sponsor that the test article meets all necessary transport regulations, particularly those regulations involving the carriage of hazardous goods and the import/export of goods or equipment, and that any costs including tax/duty were fully met by the Sponsor prior to receipt of the test article at PCR Corp. No liability with regard to safe receipt or costs involved in the carriage of goods or equipment to any PCR Corp site was accepted.

On study completion any remaining unused test articles were disposed of, unless otherwise requested by the Sponsor, after issuance of the final report or 28 days after study completion, whichever came first. Sponsors requesting the return of products were liable for any costs incurred.

7 STUDY PROCEDURE

a) Study Outline

Subjects attended the test centre at baseline (Day 1) to complete the informed consent form (ICF). Subjects were issued with the test product (according to Randomisation; Appendix 5), diary (Appendix 6) and instructions for how to use the product at home for the next 4 weeks. Subjects completed 2 Self-Perception Questionnaire (SPQ) questions daily, which were on their diary card. At the end of the study (Day 30) subjects returned to the test centre to complete an online Self-Perception Questionnaire (SPQ).

b) Test Article Use

The test articles were used at home throughout the duration of the study. According to the usage instructions (Appendix 2).

c) Self-Perception Questionnaire (SPQ)

At the end of the study subjects completed an online SPQ (Appendix 7) on how the test product improved their anxiety.

8 STUDY ETHICS**8.1 Declaration of Helsinki**

The study conformed to the requirements of the 1964 Declaration of Helsinki and its subsequent amendments (*World Medical Association; 2013*).

8.2 Subject consent

Subjects were informed of the nature, purpose and known risk of the study both orally and in writing and gave their written informed consent to participate in the study prior to any study procedures being performed (Appendix 1). Subjects were advised that they were free to withdraw from the study at any time without being obliged to give a reason. They were compensated for their time.

8.3 Indemnity Provision

The Sponsor was responsible, without regard to legal liability, and indemnified PCR Corp or any of their respective officers or employees in the event of claims for compensation from subjects suffering injury or other deterioration in health or well-being as a result of participation in this study, except and insofar as such claims arise as a result of any negligent act or omission on the part of PCR Corp employees or any persons undertaking or involved in the study by arrangement with PCR Corp.

9 RESULTS

9.1 Location and dates of the study

The study was performed at PCR Corp, between 5th September 2016 and 4th October 2016.

9.2 Subjects

Fifty (50) male and female subjects were enrolled onto the study and fifty (50) subjects completed the study.

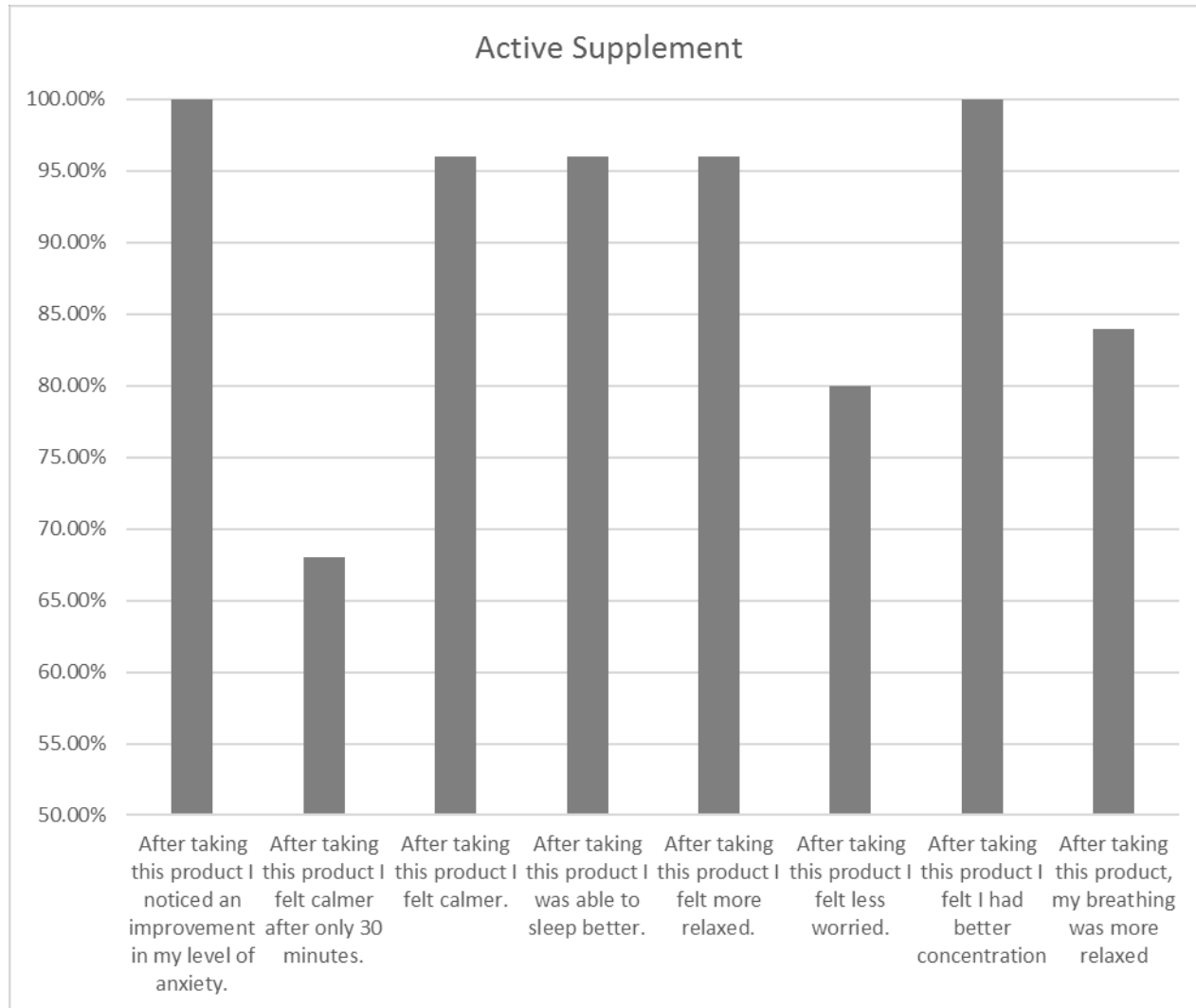
9.3 Adverse events, adverse reactions and subjects not completing the study

No Adverse Events were reported.

9.4 Conclusions

As can be seen from the data the product performed highly favourably under Clearcast guidelines, over the 30 day testing period shown by Top 2 responses (Strongly Agree + Agree) being >80% (regarded as highly favourable). The Sponsor's product also performed statistically significantly better than the Placebo product for all comparable questions. With 100% of subjects noticing an improvement in their level of anxiety and 68% of subjects felt calmer after only 30 minutes.

Bar Graphs over page show the percentage of subjects that gave the top two responses (Strongly Agrees + Agrees) for the Active Supplement.



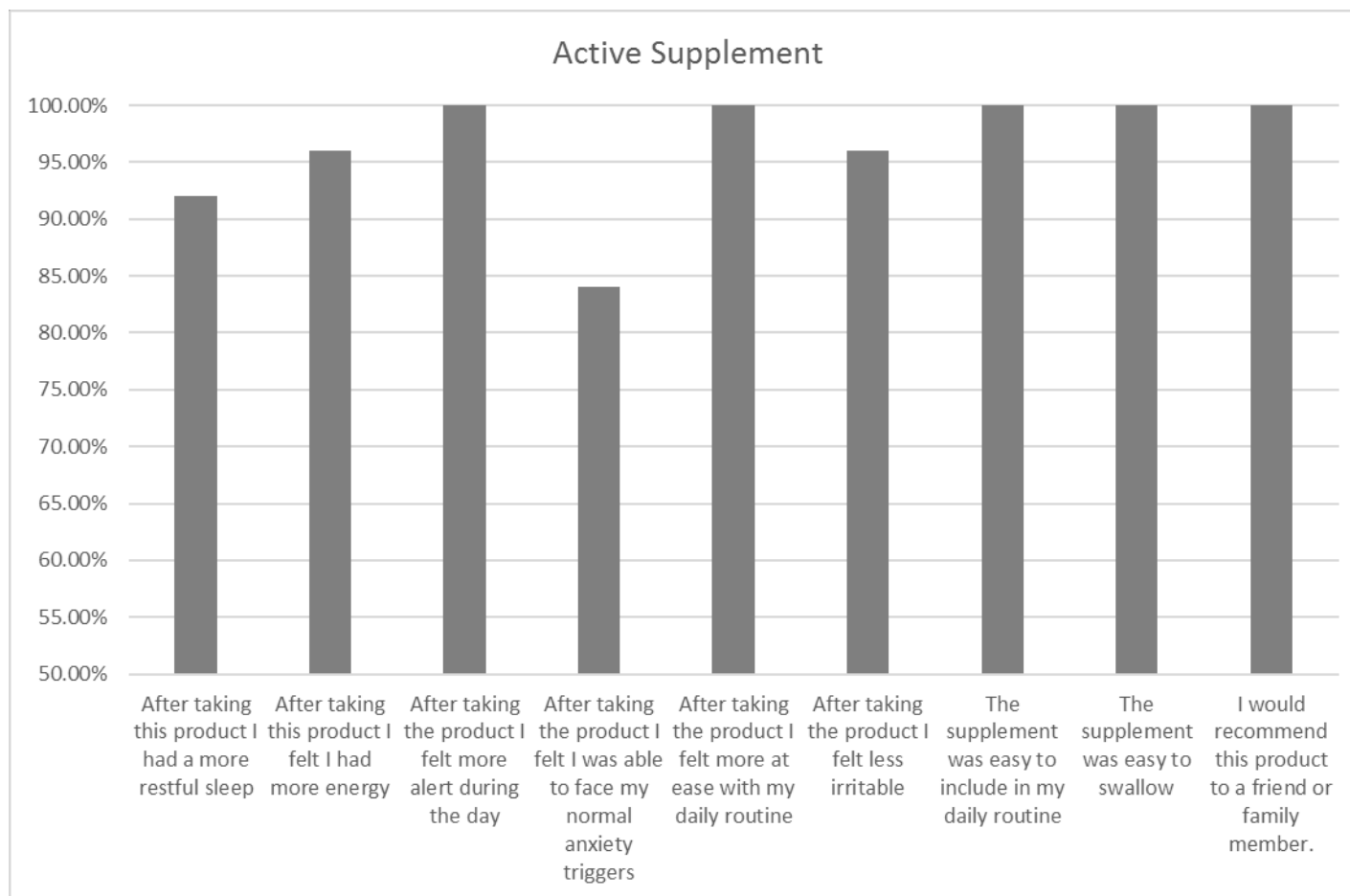


Table 1: Summary of % Responses for the Product Tested

Question	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
After taking this product I noticed an improvement in my level of anxiety.	28	72	0	0	0
After taking this product I felt calmer after only 30 minutes.	8	60	28	4	0
After taking this product I felt calmer.	28	68	4	0	0
After taking this product I was able to sleep better.	8	88	4	0	0
After taking this product I felt more relaxed.	28	68	4	0	0
After taking this product I felt less worried.	12	68	20	0	0
After taking this product I felt I had better concentration	24	76	0	0	0
After taking this product, my breathing was more relaxed	16	68	12	4	0
After taking this product I had a more restful sleep	12	80	8	0	0
After taking this product I felt I had more energy	32	64	4	0	0
After taking the product I felt more alert during the day	24	76	0	0	0
After taking the product I felt I was able to face my normal anxiety triggers	8	76	12	4	0
After taking the product I felt more at ease with my daily routine	24	76	0	0	0
After taking the product I felt less irritable	28	68	4	0	0
The supplement was easy to include in my daily routine	48	52	0	0	0
The supplement was easy to swallow	36	64	0	0	0
I would recommend this product to a friend or family member.	56	44	0	0	0

Table 2: Statistical Analysis – Paired TTest of Treatment vs Placebo

Question No.	1	2	3	4	5	6	7	8				
A vs B	1.28E-03	2.52E-02	1.74E-04	1.10E-04	1.07E-03	1.19E-03	9.73E-04	2.21E-04				
Question No.	9	10	11	12	13	14	15	16	17	18	19	20
A vs B	2.00E-04	2.41E-03	5.58E-05	9.73E-04	2.64E-04	1.22E-04	3.17E-02	2.00E-02	N/A	1.76E-04	N/A	N/A

P<0.05 shows that the subject's perception of treatment product was statistically significantly better than the subject's perception of the placebo product.

APPENDIX 1: SUBJECT CONSENT FORM

Study Code: NUTUSE1M

Subject #: _____

INTRODUCTION

You are being asked for your consent to participate in a research study. Prior to giving your consent, it is important that you take the time to read and understand what participation will involve. This consent form may contain technical language which you may not understand. If you do not understand any of this consent form, please ask the clinical staff any questions you may have.

You will be provided with a signed copy of this consent form and any other necessary written information prior to the start of the study.

OBJECTIVE

The objective of this research study is to determine the efficacy of one test article at reducing anxiety.

TEST ARTICLES

The test article is a nutritional supplement. The test article used will be through normal everyday use following usage instructions provided.

STUDY PROCEDURES

You will be one of approximately 50 subjects enrolled onto this study. Your participation in this study will last approximately four weeks (30 Days) and will include two visits to the testing facility.

Visit 1 (*Study day 1 – approximately 30 minutes*): Prior to acceptance on the study, you will be screened for eligibility to participate on the study and on confirmed eligibility consented to participate. Following verification of your acceptance and your written consent, you will be issued with the test product (with usage instructions and diary) to use at home for the next four weeks. You will need to answer the 2 questions of your diary card every day.

Visits 2 (*Study day 30 – approximately 15 minutes*): You will attend the study centre to complete an online questionnaire, return any unused test product and receive compensation.

RISKS

To the best of our knowledge, these products are not expected to induce an allergic reaction. While the potential for irritation or other reactions during this study are minimal, it is possible for a reaction to occur. Expected reactions for these test articles categories are mild in nature and may include the following: redness, itching, peeling or blistering. In addition to the risks described, there may be other risks that are currently unforeseeable.

No significant adverse reactions are expected to occur. However, if you develop an adverse reaction or complication as a result of your participation in this study, medical treatment will be provided by clinical staff nurses at PCR CORP or you will be referred for appropriate treatment at no cost to you, as long as you have followed the study instructions. Provisions of such medical care is not an admission of legal responsibility. You will be followed by PCR CORP until the adverse reaction has resolved. No additional compensation will be available to you. Neither the sponsoring company nor the investigating company will be held responsible for any future medical expenses.

APPENDIX 1 – CONTINUED

BENEFITS

While it is likely that you will not receive any direct benefit from your participation in the study, the study results may have the potential to increase scientific knowledge about nutritional supplements and may allow for new and improved products to be marketed.

CONFIDENTIALITY

Information concerning you that is obtained in connection with this study will be kept confidential by PCR CORP, except that the sponsoring company whose product is being tested will receive a copy of the study records. The records will be uniquely coded to protect your and your child's identity. In addition, third party regulatory authorities, including the U.S. Food and Drug Administration (FDA), may inspect the records of the study. In all cases, your confidentiality will be maintained and your identity will remain private.

Your signature on the Informed Consent provides your permission for these agencies to view your personal information and the study data.

NEW FINDINGS

Any new information that is discovered during the study and which may influence your willingness to continue in the study will be made available to you.

MEDICAL TREATMENT

In the event of an emergency, dial 999. If you receive any medical care during the course of the study, inform medical personnel that your participating in a research study. Please contact PCR CORP staff as soon as possible to inform them of your condition.

WHO TO CONTACT

If you have any questions about this study or in the case of an emergency, contact **Andy King** on **01245 934050** during normal business hours.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this research study is strictly voluntary. You may refuse to participate or may discontinue participation at any time during the study without penalty or loss of benefits to which you are otherwise entitled. However, you must contact the test facility and inform a clinical staff member of your decision to withdraw from the study.

If you agree to participate in the study, you are also agreeing to provide PCR CORP with accurate information and to follow study instructions as given to you. If you fail to follow study instructions, you may be asked to discontinue participation.

Your participation in the study may be discontinued at any time without your consent by PCR CORP, regulatory agencies, or the sponsoring company for reasons of but not limited to a severe side effect and accompanying illness, or if you do not follow study instructions.

COMPENSATION

If you agree to your participation in this study, you will be paid £XX upon completion of the study.

APPENDIX 2: SUBJECT INFORMATION SHEET – NUTUSE1M

Study Code: NUTUSE1M

You have agreed to your participation in a research study. By agreeing to participate, you are also agreeing to the following prohibitions and restrictions:

- Subjects agree to use the trial product assigned as instructed, instead of their usual brand for the duration of the study.

The study schedule is as follows:

Monday 5 th Sept	Tuesday – Sunday (Week 1) 6 th – 11 th Sept
Visit 1 –	Use product at home, as instructed.
Completion of informed consent.	Answer 2 questions on diary card.
Issue products, instructions and diary	
Monday – Sunday (Week 2) 12 th – 18 th Sept	
	Use product at home, as instructed.
	Answer 2 questions on diary card.
Monday – Sunday (Week 3) 19 th – 25 th Sept	
	Use product at home, as instructed.
	Answer 2 questions on diary card.
Monday – Monday (Week 4) 26 th – 3 rd Oct	
	Use product at home, as instructed.
	Answer 2 questions on diary card.
Tuesday 4 th Oct	
Visit 2 –	
Study End SPQ Completion	
Product Return	
Compensation	

Please follow the usage instructions below:

Directions: Take 2 capsules in the morning, per day for 30 days which can be taken with or without food. Please DO NOT open the capsules.

*You must come in for all visits; no misses will be allowed. If you are unable to come in for a visit, your participation will be discontinued. Upon completion of this study on 4th October 2016, you will receive £XX for your participation.

If you have any questions about this study or in the case of a suspected allergic reaction, call Andy King on 01245 934050 during normal business hours.

APPENDIX 3: PRE-TREATMENT QUESTIONNAIRE

FOR OFFICE USE ONLY		
SUBJECT'S INITIALS		
MALE/FEMALE		
AGE		
SUBJECT NUMBER		

Study Code: NUTUSE1MSTRICTLY CONFIDENTIAL

Inclusion Criteria		Yes	No
1.	Healthy male and female volunteers, aged over 18 years, with self-assessed anxiety.	<input type="checkbox"/>	<input type="checkbox"/>
2.	Subject has completed a written informed consent.	<input type="checkbox"/>	<input type="checkbox"/>
Exclusion Criteria		Yes	No
1.	Subject is pregnant, nursing, or planning to become pregnant	<input type="checkbox"/>	<input type="checkbox"/>
2.	A current skin disease of any type at the test site (e.g. eczema, psoriasis)	<input type="checkbox"/>	<input type="checkbox"/>
3.	History of malignant disease	<input type="checkbox"/>	<input type="checkbox"/>
4.	Significant past medical history of hepatic, renal, cardiac, pulmonary, digestive, haematological, neurological, locomotor or psychiatric disease, which in the opinion of the Investigator would compromise the safety of the subject;	<input type="checkbox"/>	<input type="checkbox"/>
5.	History of asthma requiring regular medication.	<input type="checkbox"/>	<input type="checkbox"/>
6.	Known sensitivity to the test article, similar materials or their constituents.	<input type="checkbox"/>	<input type="checkbox"/>
7.	Current participation in a clinical trial or follow-up.	<input type="checkbox"/>	<input type="checkbox"/>
Prohibitions and Restrictions		Yes	No
1.	Subjects agree to use the trial product assigned as instructed, instead of their usual brand for the duration of the study.	<input type="checkbox"/>	<input type="checkbox"/>

APPENDIX 3 – CONTINUED

Have you ever had any skin problems related to the use of any of the following types of material?

Material	Yes			No	When? – Which products? – What happens?
Nutritional Supplements					
Other Personal Care Products – please specify					

Questionnaire checked and confirmed by:

Signature

Date

PCR CORP

APPENDIX 4: TEST ARTICLES INCI LISTINGSActive Supplement

Ingredients:

350 mg total of Redicalm proprietary blend: L-Theanine, Ashwagandha Powder, Lemon Balm Powder, Passion Flower Powder, 5 HTP.

Other ingredients: Vegetable capsule (capsule shell), Rice Flour, Magnesium Stearate.

Placebo Supplement

Ingredients:

Gelatin capsule (capsule shell).

APPENDIX 5: RANDOMISATION

SUBJECT NUMBER	PRODUCT	SUBJECT NUMBER	PRODUCT
1	A	27	B
2	A	28	B
3	A	29	A
4	A	30	A
5	B	31	B
6	A	32	B
7	A	33	B
8	B	34	A
9	B	35	B
10	B	36	A
11	A	37	B
12	B	38	A
13	A	39	B
14	B	40	B
15	B	41	A
16	A	42	A
17	A	43	B
18	B	44	B
19	B	45	A
20	A	46	A
21	B	47	A
22	A	48	A
23	B	49	A
24	B	50	A
25	B	51	A
26	B	52	B

APPENDIX 6: SUBJECT DIARY

Please take the test product supplied to you as instructed, **2 CAPSULES ONCE A DAY.**

Please answer the 2 questions in the table every day, following the answer key below.

If you have any problems with the product please call the office at 01245 934050 during business hours, 9:00am to 5:00pm.

PLEASE USE BLACK INK

Day	Date	Did you take 2 capsules? <input checked="" type="checkbox"/> Check Box	If NO, explain why	Q1 - After taking this product I noticed an improvement in my level of anxiety.	Q2 - After taking this product I felt calmer after only 30 minutes
1		<input type="checkbox"/> Yes <input type="checkbox"/> No			
2		<input type="checkbox"/> Yes <input type="checkbox"/> No			
3		<input type="checkbox"/> Yes <input type="checkbox"/> No			
4		<input type="checkbox"/> Yes <input type="checkbox"/> No			
5		<input type="checkbox"/> Yes <input type="checkbox"/> No			
6		<input type="checkbox"/> Yes <input type="checkbox"/> No			
7		<input type="checkbox"/> Yes <input type="checkbox"/> No			
8		<input type="checkbox"/> Yes <input type="checkbox"/> No			
9		<input type="checkbox"/> Yes <input type="checkbox"/> No			
10		<input type="checkbox"/> Yes <input type="checkbox"/> No			
11		<input type="checkbox"/> Yes <input type="checkbox"/> No			
12		<input type="checkbox"/> Yes <input type="checkbox"/> No			
13		<input type="checkbox"/> Yes <input type="checkbox"/> No			
14		<input type="checkbox"/> Yes <input type="checkbox"/> No			
15		<input type="checkbox"/> Yes <input type="checkbox"/> No			
16		<input type="checkbox"/> Yes <input type="checkbox"/> No			
17		<input type="checkbox"/> Yes <input type="checkbox"/> No			
18		<input type="checkbox"/> Yes <input type="checkbox"/> No			
19		<input type="checkbox"/> Yes <input type="checkbox"/> No			
20		<input type="checkbox"/> Yes <input type="checkbox"/> No			
21		<input type="checkbox"/> Yes <input type="checkbox"/> No			
22		<input type="checkbox"/> Yes <input type="checkbox"/> No			
23		<input type="checkbox"/> Yes <input type="checkbox"/> No			
24		<input type="checkbox"/> Yes <input type="checkbox"/> No			
25		<input type="checkbox"/> Yes <input type="checkbox"/> No			
26		<input type="checkbox"/> Yes <input type="checkbox"/> No			
27		<input type="checkbox"/> Yes <input type="checkbox"/> No			
28		<input type="checkbox"/> Yes <input type="checkbox"/> No			
29		<input type="checkbox"/> Yes <input type="checkbox"/> No			
30		<input type="checkbox"/> Yes <input type="checkbox"/> No Please bring back the product and daily.			

Answer Key for the 2 questions:

Strongly Disagree = 1

Disagree = 2

Neither Agree or Disagree = 3

Agree = 4

Strongly Agree = 5

Comments: _____

PCR CORP

APPENDIX 7: SELF-PERCEPTION QUESTIONNAIRE

NUTUSE1M: Self-Perception Questionnaire (Post-Treatment)

Subject details

Initials

Age

Q1 After taking this product I noticed an improvement in my level of anxiety.

- Strongly disagree.....
- Disagree.....
- Neither agree nor disagree.....
- Agree.....
- Strongly agree.....

Q6 After taking this product I felt less worried.

- Strongly disagree.....
- Disagree.....
- Neither agree nor disagree.....
- Agree.....
- Strongly agree.....

Q2 After taking this product I felt calmer after only 30 minutes.

- Strongly disagree.....
- Disagree.....
- Neither agree nor disagree.....
- Agree.....
- Strongly agree.....

Q7 After taking this product I felt I had better concentration

- Strongly disagree.....
- Disagree.....
- Neither agree nor disagree.....
- Agree.....
- Strongly agree.....

Q3 After taking this product I felt calmer.

- Strongly disagree.....
- Disagree.....
- Neither agree nor disagree.....
- Agree.....
- Strongly agree.....

Q8 After taking this product, my breathing was more relaxed

- Strongly disagree.....
- Disagree.....
- Neither agree nor disagree.....
- Agree.....
- Strongly agree.....

Q4 After taking this product I was able to sleep better.

- Strongly disagree.....
- Disagree.....
- Neither agree nor disagree.....
- Agree.....
- Strongly agree.....

Q9 After taking this product I had a more restful sleep

- Strongly disagree.....
- Disagree.....
- Neither agree nor disagree.....
- Agree.....
- Strongly agree.....

Q5 After taking this product I felt more relaxed.

- Strongly disagree.....
- Disagree.....
- Neither agree nor disagree.....
- Agree.....
- Strongly agree.....

Q10. After taking this product I felt I had more energy

- Strongly disagree.....
- Disagree.....
- Neither agree nor disagree.....
- Agree.....
- Strongly agree.....

Self-Perception Questionnaire - Continued

Q11 After taking the product I felt more alert during the day

- Strongly disagree.....
- Disagree.....
- Neither agree nor disagree.....
- Agree.....
- Strongly agree.....

Q12 After taking the product I felt I was able to face my normal anxiety triggers

- Strongly disagree.....
- Disagree.....
- Neither agree nor disagree.....
- Agree.....
- Strongly agree.....

Q13 After taking the product I felt more at ease with my daily routine

- Strongly disagree.....
- Disagree.....
- Neither agree nor disagree.....
- Agree.....
- Strongly agree.....

Q14 After taking the product I felt less irritable

- Strongly disagree.....
- Disagree.....
- Neither agree nor disagree.....
- Agree.....
- Strongly agree.....

Q15 The supplement was easy to include in my daily routine

- Strongly disagree.....
- Disagree.....
- Neither agree nor disagree.....
- Agree.....
- Strongly agree.....

Q16 The supplement was easy to swallow

- Strongly disagree.....
- Disagree.....
- Neither agree nor disagree.....
- Agree.....
- Strongly agree.....

Q17 My usual supplement for my anxiety is:

.....

.....

Q18 I would recommend this product to a friend or family member.

- Strongly disagree.....
- Disagree.....
- Neither agree nor disagree.....
- Agree.....
- Strongly agree.....

Q19 Is there anything about this product you like?

.....

.....

.....

Q20 Is there anything about this product you dislike?

.....

.....

.....

APPENDIX 8: SELF-PERCEPTION QUESTIONNAIRE INDIVIDUAL RESPONSES – TEST SUPPLEMENT

Responses Key: 1=Strongly disagree; 2=Disagree; 3=Neither agree nor disagree; 4=Agree; 5=Strongly agree

Product Code	Subject number	Age	Q1	Q2	Q3	Q4	Q5	Q6
			After taking this product I noticed an improvement in my level of anxiety	After taking this product I felt calmer after only 30 minutes	After taking this product I felt calmer	After taking this product I was able to sleep better	After taking this product I felt more relaxed	After taking this product I felt less worried
A	1	46	4	4	5	4	4	4
A	2	50	4	4	4	4	4	4
A	3	32	4	4	5	4	5	5
A	4	29	4	4	4	4	4	4
A	6	47	4	3	4	4	4	4
A	7	35	4	4	4	4	4	3
A	11	53	5	3	5	4	4	5
A	13	28	4	4	4	4	4	4
A	16	41	5	4	4	3	4	4
A	17	28	5	3	4	4	5	4
A	20	37	4	4	4	4	4	3
A	22	36	4	3	5	4	4	4
A	29	34	4	4	4	4	4	4
A	30	49	4	3	4	4	5	3
A	34	18	4	4	5	4	4	3
A	36	46	5	4	5	4	4	4
A	38	26	4	4	4	4	5	4
A	41	62	4	5	4	4	5	4
A	42	41	5	4	5	5	5	5
A	45	32	4	4	4	4	4	4
A	46	36	4	2	4	4	4	3
A	47	31	5	3	4	5	5	4
A	48	53	5	4	4	4	4	4
A	49	25	4	3	3	4	3	4
A	50	36	4	5	4	4	4	4
Strongly Agree			28.00%	8.00%	28.00%	8.00%	28.00%	12.00%
Agree			72.00%	60.00%	68.00%	88.00%	68.00%	68.00%
Neither Agree Nor Disagree			0.00%	28.00%	4.00%	4.00%	4.00%	20.00%
Disagree			0.00%	4.00%	0.00%	0.00%	0.00%	0.00%
Strongly Disagree			0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Top 2 Responses			100.00%	68.00%	96.00%	96.00%	96.00%	80.00%

APPENDIX 8 - CONTINUED

Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14
After taking this product I felt I had better concentration	After taking this product, my breathing was more relaxed	After taking this product I had a more restful sleep	After taking this product I felt I had more energy	After taking this product I felt more alert during the day	After taking the product I felt I was able to face my normal anxiety triggers	After taking this product I felt more at ease with my daily routine	After taking the product I felt less irritable
4	4	3	4	5	4	4	4
4	4	4	4	4	4	4	4
5	4	4	4	4	4	5	4
4	4	4	4	4	4	4	4
4	4	4	4	5	4	4	4
4	4	4	4	4	4	4	4
4	4	4	5	5	4	5	5
5	4	4	5	4	4	4	4
4	3	3	4	5	4	5	4
4	5	4	4	4	3	4	5
4	3	4	4	4	2	4	4
4	4	4	5	4	5	5	4
4	5	5	4	4	4	4	4
4	4	5	5	4	4	4	4
4	4	4	4	4	3	4	4
5	4	4	4	4	4	5	5
4	4	4	4	4	4	4	4
4	3	4	5	4	4	4	5
5	4	5	5	5	4	4	5
4	4	4	4	4	4	4	4
4	4	4	4	4	4	4	3
5	5	4	5	5	5	5	5
4	5	4	4	4	4	4	5
4	2	4	3	4	3	4	4
5	4	4	5	4	4	4	4
24.00%	16.00%	12.00%	32.00%	24.00%	8.00%	24.00%	28.00%
76.00%	68.00%	80.00%	64.00%	76.00%	76.00%	76.00%	68.00%
0.00%	12.00%	8.00%	4.00%	0.00%	12.00%	0.00%	4.00%
0.00%	4.00%	0.00%	0.00%	0.00%	4.00%	0.00%	0.00%
0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
100.00%	84.00%	92.00%	96.00%	100.00%	84.00%	100.00%	96.00%

Q15 The supplement was easy to include in my daily routine	Q16 The supplement was easy to swallow	Q17 My usual supplement for my anxiety is:	Q18 I would recommend this product to a friend or family member	Q19 Is there anything about this product you like?	Q20 Is there anything about this product you dislike?
5	4	Kalms	4		
4	4	Wellman	4		
5	4		5	really good would recommend	
4	4	Multi Vitimans	4	Good product	
5	4		4	Enjoyed using it	
4	4	Holland & Barrett	4		
5	4	Kalms	5	Brilliant Product	
4	4		5	Really good	
5	4		5	Would buy this	
4	5		4		
4	4	Holland & Barrett	5	Worked a treat	
5	5	Natures Way	5		
4	4		4		
4	4	Day and Night	5		
5	5	Boots Supplements	5	Gave me a boost	
5	5	Holland & Barrett	5	Fantastic	
4	4	Nutra plus	4	Really good	
5	5	Anxiety Ease	5	Really good	
5	5	Herbal Plus	5	Brilliant	
4	4		4		
4	5	Vitabiotics	5	Would purchase really good	
5	5		5	Fantastic supplement	
5	5	natural supplements	5	Worked Well Brilliant Product	
4	4	Local Herbalist	4	Easy to swallow	Taste
4	4		4		
48.00%	36.00%		56.00%		
52.00%	64.00%		44.00%		
0.00%	0.00%		0.00%		
0.00%	0.00%		0.00%		
0.00%	0.00%		0.00%		
100.00%	100.00%		100.00%		

APPENDIX 9: SELF-PERCEPTION QUESTIONNAIRE INDIVIDUAL – PLACEBO

Product Code	Subject number	Age	Q1	Q2	Q3	Q4	Q5	Q6
			After taking this product I noticed an improvement in my level of anxiety	After taking this product I felt calmer after only 30 minutes	After taking this product I felt calmer	After taking this product I was able to sleep better	After taking this product I felt more relaxed	After taking this product I felt less worried
B	5	19	4	3	4	2	4	3
B	8	37	4	2	4	3	4	3
B	9	23	3	3	4	3	4	3
B	10	46	4	4	4	4	4	4
B	12	42	4	4	4	2	3	3
B	14	31	4	4	4	4	3	3
B	15	35	4	3	4	3	4	3
B	18	30	3	3	3	2	3	3
B	19	26	4	4	4	4	4	2
B	21	49	3	2	4	2	4	4
B	23	43	4	4	4	4	4	4
B	24	45	4	2	4	2	3	3
B	25	38	4	4	4	4	4	3
B	26	46	3	3	3	3	3	2
B	27	29	4	4	4	4	4	4
B	28	21	4	4	4	3	3	4
B	31	31	4	2	3	4	4	2
B	32	48	4	4	4	2	4	3
B	33	52	4	3	4	4	4	4
B	35	24	4	4	4	3	4	4
B	37	19	4	4	4	4	4	4
B	39	59	2	2	2	2	2	2
B	40	24	4	4	4	4	4	4
B	43	23	4	3	3	4	4	4
B	44	40	3	2	3	2	2	2
Strongly Agree			0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Agree			76.00%	48.00%	76.00%	44.00%	68.00%	40.00%
Neither Agree Nor Disagree			20.00%	28.00%	20.00%	24.00%	24.00%	40.00%
Disagree			4.00%	24.00%	4.00%	32.00%	8.00%	20.00%
Strongly Disagree			0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Top 2 Responses			76.00%	48.00%	76.00%	44.00%	68.00%	40.00%

APPENDIX 9 - CONTINUED

Q7 After taking this product I felt I had better concentration	Q8 After taking this product, my breathing was more relaxed	Q9 After taking this product I had a more restful sleep	Q10 After taking this product I felt I had more energy	Q11 After taking this product I felt more alert during the day	Q12 After taking the product I felt I was able to face my normal anxiety triggers	Q13 After taking this product I felt more at ease with my daily routine	Q14 After taking the product I felt less irritable
4	4	3	4	3	3	4	4
4	3	2	3	4	3	3	4
3	3	3	3	3	3	3	4
4	4	4	4	4	4	4	4
4	3	2	4	4	3	3	4
4	3	4	4	4	2	4	3
3	4	3	3	4	3	4	4
3	2	3	3	3	3	4	3
4	3	4	4	4	4	4	4
3	3	1	3	3	2	3	3
4	4	4	4	4	4	4	4
4	3	4	3	3	4	4	3
4	4	4	4	4	3	4	3
3	3	3	3	3	3	3	2
4	4	4	4	4	4	4	4
3	3	3	4	4	4	3	4
3	3	4	4	3	3	4	3
3	3	3	4	4	3	4	3
3	3	4	4	4	3	4	4
4	3	3	4	4	4	4	5
4	2	4	4	4	4	3	3
2	2	2	2	2	2	2	3
4	2	3	4	4	2	3	3
4	3	4	4	3	3	4	3
2	3	3	2	3	2	2	3
0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	4.00%
56.00%	24.00%	44.00%	64.00%	56.00%	32.00%	60.00%	44.00%
36.00%	60.00%	40.00%	28.00%	40.00%	48.00%	32.00%	48.00%
8.00%	16.00%	12.00%	8.00%	4.00%	20.00%	8.00%	4.00%
0.00%	0.00%	4.00%	0.00%	0.00%	0.00%	0.00%	0.00%
56.00%	24.00%	44.00%	64.00%	56.00%	32.00%	60.00%	48.00%

Q15 The supplement was easy to include in my daily routine	Q16 The supplement was easy to swallow	Q17 My usual supplement for my anxiety is:	Q18 I would recommend this product to a friend or family member	Q19 Is there anything about this product you like?	Q20 Is there anything about this product you dislike?
5	5		4		
5	4		4	Easy to swallow	
4	4	natural care	3		Didn't feel much difference
4	4		4	Liked it	
5	4	Multi Vitimans	3	was ok	
4	3		4	Easy to swallow	Were bland
4	4		4		
4	4	Herbs & Vitimans	3		I Prefer What I Use
4	4	Herbal Plus	5		
4	4	Natures	4		
4	4	Holistic Herbs	4		
5	4	Kalms	4		
4	5	Holland & Barrett	5	Thought they were good	
4	4	Optima	2		Did not do anything for me
4	4	Pure Natural	4		
4	2	Vitabiotics	4		
4	5	Kalms	4		
4	4		3		
4	3	Multi Vitimans	4		
5	4	Vitamins from various supermarkets	4		
4	4		4		
4	3	Pure	2		
4	4	Holland & Barrett	3	was easy to swallow	
4	4		4		
4	3	Kalms	2		No affect on me
20.00%	12.00%		8.00%		
80.00%	68.00%		60.00%		
0.00%	16.00%		20.00%		
0.00%	4.00%		12.00%		
0.00%	0.00%		0.00%		
100.00%	80.00%		68.00%		