

IQoro Neuromuscular Training – Patient Reported Outcomes

- A report on user-reported experiences

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Overview

Need for further evidence

Clinicians, health authorities and others are always keen to have more data and evidence to support the efficacy of IQoro as a treatment. The manufacturer is able to point to more than a dozen peer-reviewed and internationally-published scientific studies as well as service evaluations and case studies that have been presented internationally

<https://clinicians.iqoro.com/evidence/> .

However, in addition to this there is now a far greater body of evidence that has been collected over the previous four years in the form of user responses to a standard annual questionnaire.

Questionnaire design

The questions used were designed to inform the manufacturer and others on several aspects of customer behaviour and results. Some were directed at gathering marketing data, for example on customer demographics, how they first heard about IQoro, what persuaded them to start using it, etc. Other questions were related to conditions treated, outcomes, ease of use and compliance.

It is this latter category of questions that are analysed and presented here.

Limitations of this evidence

The questionnaire was designed, issued and administered by the company, no independent input or review was included.

I have been personally responsible for consolidating, analysing and presenting the data in this report. I have made every effort to do so fairly and impartially.

The majority of users, especially in the earlier years, self-purchased the device rather than having had issued it on prescription. There may be a bias towards people who have invested their own money in the treatment exhibiting better compliance than those who received it for free. But where the prescribing doctor has chosen her patient for treatment carefully this bias may not exist.

Any other usual limitations of patient reported outcome data will also be present here.

Strengths of this evidence

The questionnaire presents the responses of 14,570 users of the device, all in recent history and across the full range of aetiologies treated. It presents real-life user data from a range of European countries.

Questionnaire design and coverage

The first questionnaire was sent at midsummer 2018, and subsequent versions were sent at the same time of year in the succeeding five years. With the exception of the first two years the questions have been almost unchanged and thus it is these last four years' responses that I have consolidated and tabulated here.

The survey was sent to all those users that we could identify that had received their IQoro within the previous 12 months, and for whom we had an e-mail address. No other criteria were applied to exclude respondents.

Users known to be in Sweden were sent a questionnaire in the Swedish language, all others in the UK and rest of Europe received an English language version. The two different language versions were translated and re-translated by blinded third parties to check for exact meaning

equivalence, thus all responses can be validly consolidated in this report.

Author

I have been employed by the company since 2016 and have worked intensively to promote the adoption of the treatment - especially in the UK market. The raw data from which I have worked, and my reasoning and analysis are available for inspection.

Terry W. Morris
Stockholm, Sweden
April 2024

Responses

The English and Swedish language questionnaires gained numbers of responses as follows:

	2020	2021	2022	2023	Totals
Eng	738	1,552	1,005	1,482	4,777
Swe	2,163	2,884	2,452	2,294	9,793
	2,901	4,436	3,457	3,776	14,570

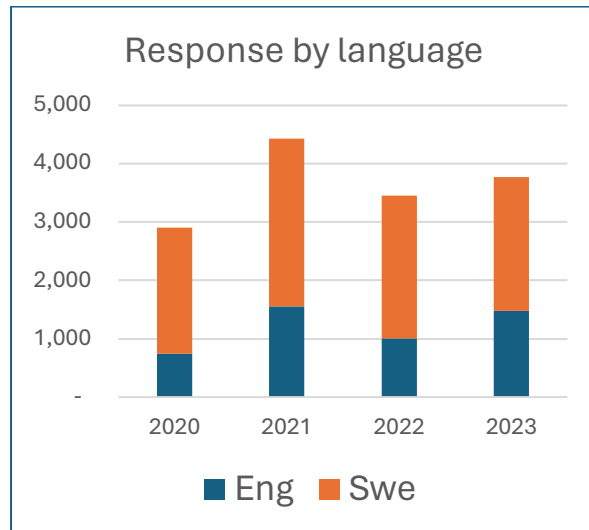


Fig. 1 Response by language. N=14,570

There was little or no difference between the two language responses from a medical condition or patient outcome perspective.

The marketing data revealed some behavioural differences in purchasing preferences.

What is IQoro used for?

Symptoms treated (all)

IQoro is a neuromuscular training device that acts on the motor cortex and the Reticular Formation, the region of the brain stem that regulates muscle activity in the autonomic nervous system.

Swallowing problems, reflux, silent reflux, facial muscle weakness, postural control and other conditions are addressed equally well by IQoro treatment and users acquire devices to treat all these conditions.

An analysis of the most common reasons for beginning IQoro training shows the following top 10 reasons for starting.

What symptoms were you suffering from when you began training with IQoro? You can choose more than one.

Symptom	
Reflux / acid reflux	8,556
Heartburn	5,113
A sensation of something stuck in your throat	4,957
Excessive or thick phlegm	4,633
Dry persistent cough	3,012
Gassy, burping often	3,078
Pain in your chest or esophagus	3,033
Food being regurgitated	1,251
Hoarseness	2,526
Difficulty in swallowing liquids safely	665
Total	36,824

The above table summarises four years' data from all countries. Because patients were allowed to choose all the symptoms that they were experiencing, the total

number of responses exceeds the population that responded.

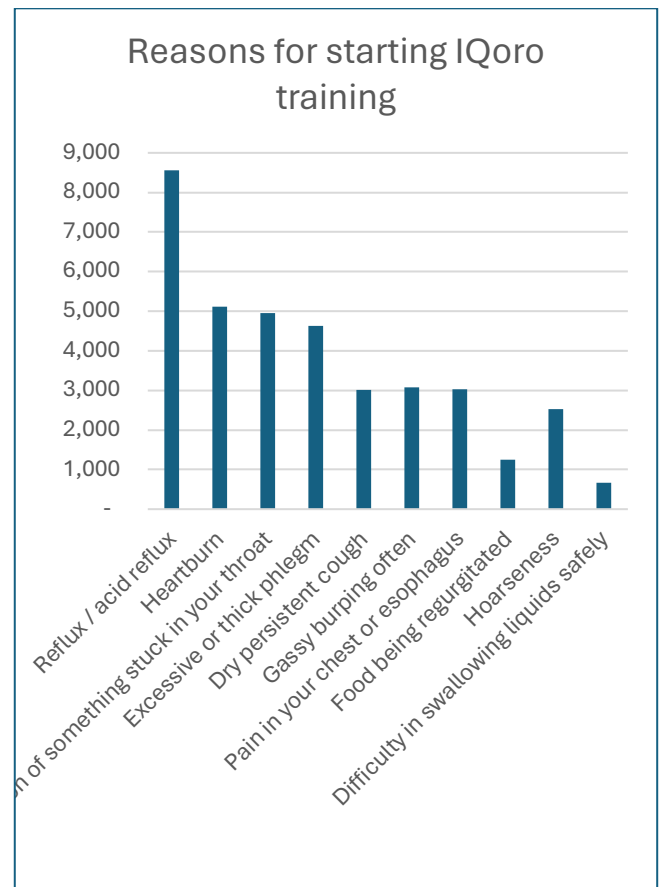


Fig. 2 Reasons for starting IQoro treatment. N=36,824

Other conditions reported included difficulty in swallowing certain foods, facial weakness after stroke and more. but I have limited this analysis to the “Top 10” conditions.

The overall conclusion is that a wide range of symptoms are being treated, and that reflux accounts for the majority.

Symptoms treated (main only)

A further question asked what the *main* reason was for starting IQoro training, either by purchasing - or in a few cases in the later two years - by getting a UK prescription.

What was the main reason that you started training with IQoro? If there was more than one, give only the main reason.

Symptom	
Reflux / acid reflux	3,974
Heartburn	1,297
A sensation of something stuck in your throat	1,284
Pain in your chest or esophagus	861
Excessive or thick phlegm	572
Difficulty in swallowing food	370
Dry persistent cough	879
Gassy, burping often	234
Food being regurgitated	228
Hoarseness	794
Total	10,493

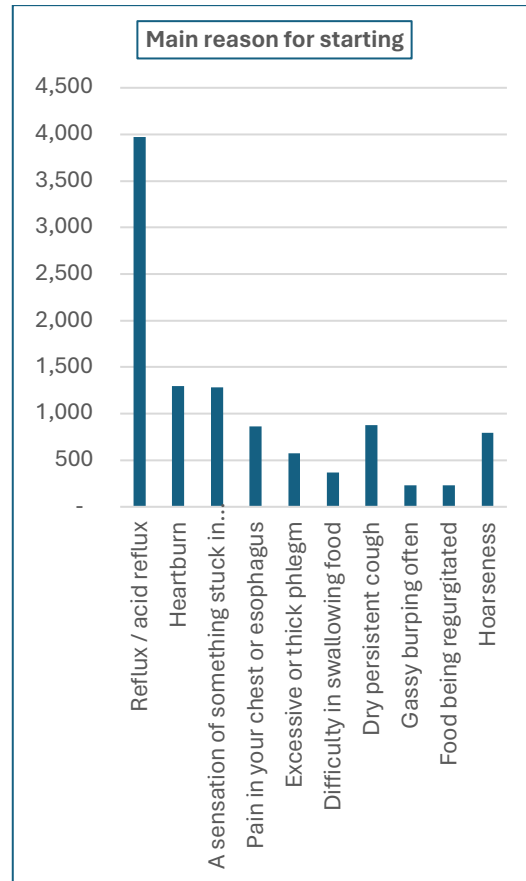


Fig. 3 Main reason for starting IQoro training. N=10,493

This response shows reflux-related conditions occupying most of the top ten positions. Gastro Oesophageal Reflux Disease (GORD)-like symptoms slightly outweighing LaryngoPharyngeal Reflux (LPR).

Training compliance

How long have users trained?

How long have you trained with IQoro?

This question asked how long respondents had trained with IQoro. Since the questionnaire was only sent to those who had acquired their device within the previous 12 months, the answers range from 0 to 12.

Months trained so far	
<1 month	739
1 - 2 months	2,414
3 - 5 months	4,304
6 - 8 months	2,969
>9 months	2,599
Haven't started	828
Total	13,853

Note that a proportion (22%) have only trained for less than 2 months: we would not always expect to see a marked improvement that soon; although the following section show that some do see initial success with some symptoms.

All future result data in this paper should be viewed through the prism of 'new starters' probably not yet being in the zone where we would expect complete positive results.



Fig 4. How long have you trained with IQoro? N=13,853

How quickly do people see initial results?

How much time did it take before you saw a positive improvement that you attribute to your IQoro training?

Months to first improvement (I)	
<1 month	1,680
1 - 2 months	3,799
3 - 5 months	2,880
6 - 8 months	633
>9 months	175
Don't remember when it started	1,621
None yet	2,054
Total	12,842

The picture is maybe clearer if we say that those that don't remember when their improvements started would answer proportionally the same as those that do remember and report. The following table allocates the 'don't remembers' across the time periods.

Months to 1st improvement (II)	
<1 month	1,977
1 - 2 months	4,471
3 - 5 months	3,389
6 - 8 months	745
>9 months	206
None yet	2,054
Total	12,842

This gives us:

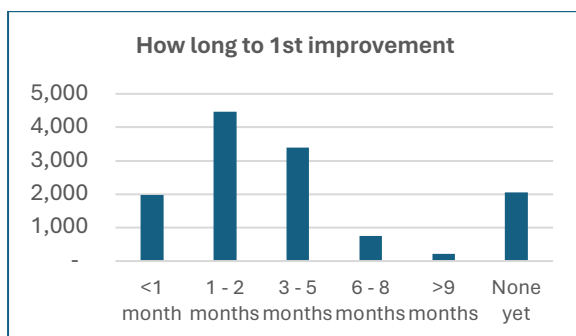


Fig. 5 How long to first sign of improvement? N=12,842

The first month accounts for 15% of responses and the second month for 35% - totally 50% within the first two months.

The period of months 3, 4 and 5 add a further 26%.

Training habits

How often do you train?

Only the last two years' questionnaire asked this question.

How often do you train?	
3 times / day. 7/7	3,413
2 - 3 times / day. >5 /7	2,137
A few times per week	670
Sporadically	464
Total	6,684

The optimal training regime for the device is 3 pulls of 10 seconds each in a session, with this session repeated 3 times per day.

The results shown in this table show 51% of respondents reporting an optimal training regime. A further 32% trained two to three times per day at least five days per week, a regime which still will show a very positive effect.

83% of users can thus be thought of as having a very satisfactory compliance rate.

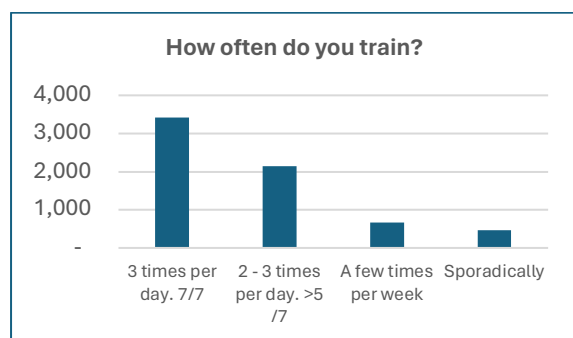


Fig. 6. How often do you train? N=6,684

Why less training than optimal?

We questioned those who had trained sub-optimally. Of course, there can be good and bad reasons for not training at the optimum level. 26% of those with sub-optimal training habits answered that they had reduced their training regime because their symptoms had gone or were reduced, whereas 74% had no positive reason and

quoted lack of success or just personal laziness.

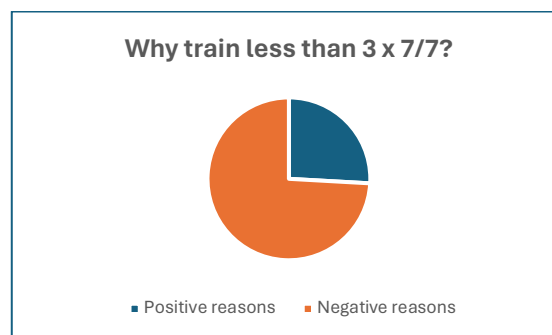


Fig. 7 Reported reasons for reduced training frequency

Compliance is of importance when considering prescription of this device, there may be a tendency for those responding in this survey to have self-purchased and thus have a further motivation to train diligently. Prescribers should consider the degree to which the patient wants to succeed with a non-medical, non-surgical solution. An earlier paragraph showed that many users see a positive improvement relatively quickly and this will provide added impetus to maintain compliance.

Ease of use & IFU

A further concern for prescribers is that of whether there will be any extra workload in explaining the device, showing how to train, or monitoring progress. All experience is that doctors can prescribe and leave the patient to collect their IQoro and follow the instructions in the instructions for use (IFU) manual included in the pack, visit the company's website to view animations and videos, or contact the company's manned helpdesk to receive further guidance and support.

Users were asked how easy it was for them to start training and answered as shown here.

It was easy to start training

Easy to start training	
Strongly agree	9,426
Partly agree	3,437
Disagree	301
Don't know	57
Total	13,221

Graphically, this looks like this. 97% said that they strongly agree, or agree.



Fig. 8 It was easy to start training? N=13,221

A further question asked if:

The training instructions were simple

The instructions were simple	
Strongly agree	9,557
Partly agree	3,243
Disagree	270
Don't know	35
Total	13,105

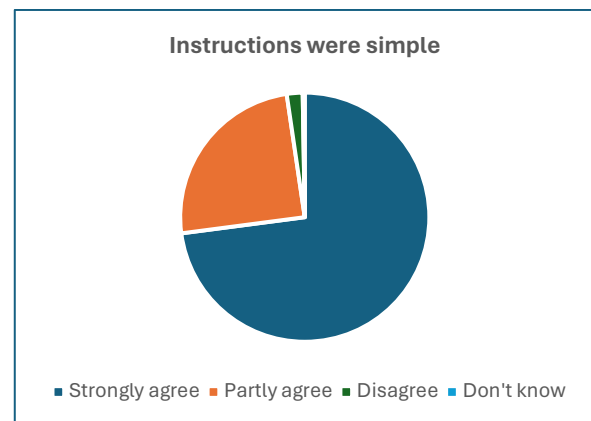


Fig. 9. The training instructions were simple? N=13,105

97% were in agreement.

A further question asked how confident users were that they were training correctly.

I feel sure that I have trained correctly

I'm sure I've trained correctly	
Strongly agree	8,679
Partly agree	3,619
Disagree	415
Don't know	382
Total	13,095

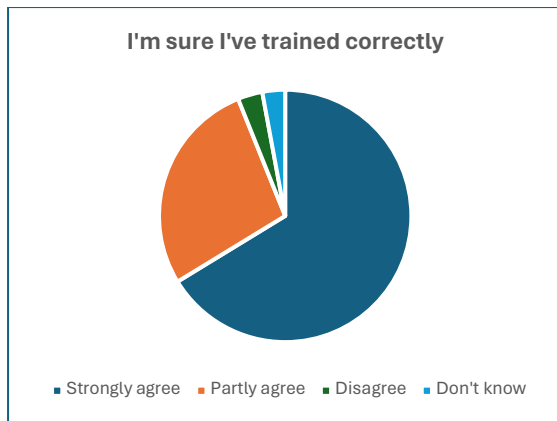


Fig. 10. I'm sure that I have trained correctly? N=13,095

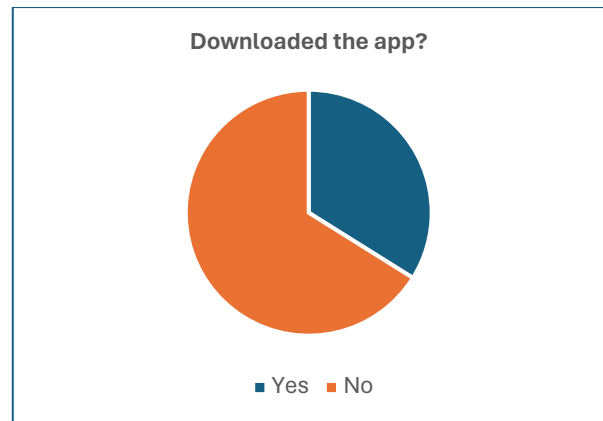


Fig. 11. Have you downloaded the app? N=6,027

The 'Strongly agree' and 'Agree' responses accounted for 66% and 27% respectively: totally 93%. The company's helpdesk is available to those unsure.

Downloaded support app

User compliance is further aided by an optional free-of-charge app that the user can download. The app reminds them of training session times, duration of training pulls and allows them to track symptom severity and improvement over time. All of this promotes the ability of the patient to self-treat without reference to a healthcare professional. The app has been available for a little over two years and this data reflect its availability in part of 2022 and all of 2023.

Have you downloaded the IQoro app?

Have you downloaded the free app?	
Yes	2,043
No	3,984
Total	6,027

What success do we see – stopping medication

Over The Counter reflux medication

Respondents were asked whether they had been able to reduce their purchase and consumption of OTC non-prescription drugs since starting to train.

I have reduced my intake of over-the-counter (store bought) medication.

Patients use anti-reflux medication to alleviate reflux symptoms. When they choose to cease or reduce dosage it can be interpreted as a proxy for reduced symptom severity.

These numbers must be read in conjunction with a previous table that shows that 22% of respondents have trained only for less than two months. This probably depresses the success of IQoro training in this picture.

We have only 3 years data only for this question.

Reduction	
Completely	1,315
Somewhat	3,452
Not at all	1,726
I never used them	2,196
Total	8,689

A more useful picture can be obtained by removing the respondents who did not use OTC medications (some of these will have been using PPI medication only).

Reduction	
Completely	1,315
Somewhat	3,452
Not at all	1,726
Total	6,493

So, of the 6,493 people that were using OTC anti-reflux medication at the time of starting training 4,762 ceased or reduced during their first 12 months.

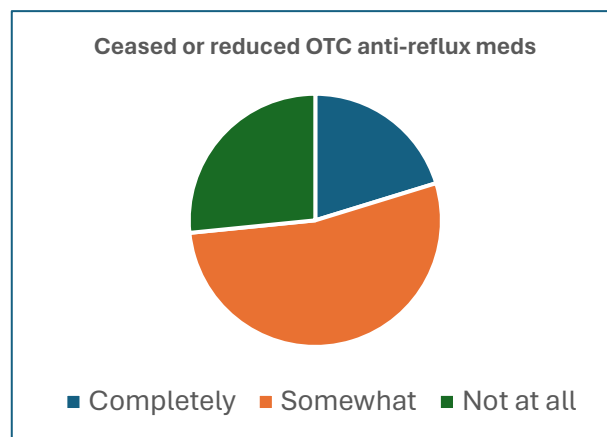


Fig. 12. Reduced intake of OTC anti-reflux drugs N=8,689

Stopped prescription medication

Similarly, users were asked:

I have reduced my intake of prescription medication (perhaps a PPI drug like Omeprazole, Lansoprazole, etc.)

There is a general pressure on prescribers in most countries to reduce prescription of PPI drugs wherever possible. They are a source of expense, require medical reviews, repeat prescription visits and have some known undesirable long term side effects. People that train with IQoro address the underlying muscular weakness that allows reflux and can expect to successfully reduce their PPI dose. The responses looked like this:

Ceased or reduced PPI intake	
Completely	1,446
Somewhat	2,349
Not at all	2,146
I never used them	2,781
Total	8,722

An important observation here is that more than 2/3 of those that started IQoro training were already on PPI drugs, usually via prescription.

If we now remove the cohort that we're not using the drugs to start with we get a more useful picture of the success of those that did.

Ceased or reduced PPI intake	
Completely	1,446
Somewhat	2,349
Not at all	2,146
Total	5,941

64% had reduced already in their first one to 12 months of IQoro training.

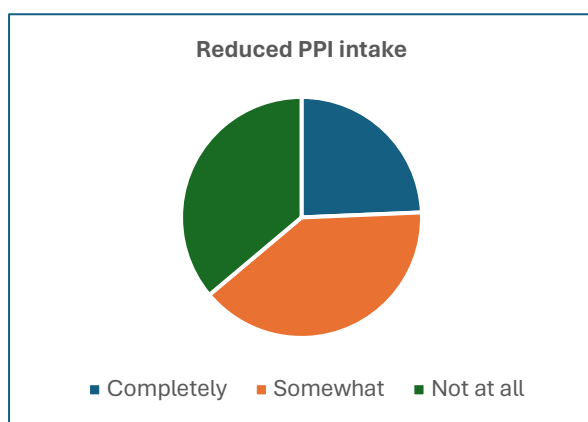


Fig. 13. Reduced intake of PPI anti-reflux drugs N=5,941

Stopped drink thickeners

People with dysphagia may have problems in swallowing liquids. A poor swallow may lead to liquid being ingested into the lungs in a process known as aspiration, once there it can become infected and is a common cause of pneumonia in dysphagic patients. It has been thought that a patient can more safely swallow a liquid if it has first been thickened by an external agent. This has a very negative effect on the attractiveness of the drink, and cost the NHS £99 million in the years 2020/21.

New thinking questions the effectiveness of drink thickeners in preventing aspiration.

Patients that train with IQoro can recover a safe swallow and usually thus reduce the

use of thickening agents. Our users were asked:

I have stopped using drink thickeners since I started training with IQoro

Ceased drink thickeners	
Completely	29
Somewhat	34
Not at all	40
I never used them	810
Total	913

The vast majority of our respondents had not used drink thickeners and were probably treating reflux-based diseases rather than dysphagia. We can get a clearer picture by removing these and looking at the 100 or so that were affected.

Ceased drink thickeners	
Completely	29
Somewhat	34
Not at all	40
Total	103

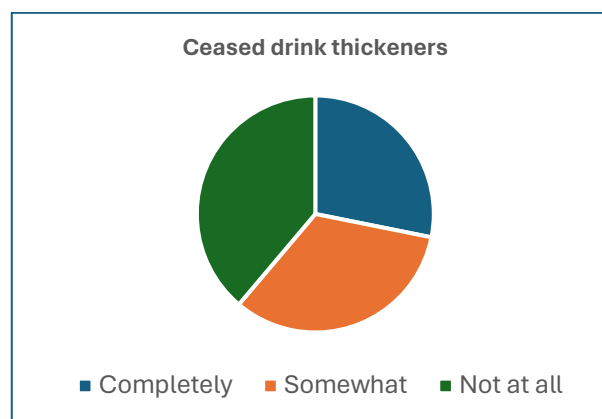


Fig. 14. Reduced use of drink thickeners N=103

Stopped modified foods

Some people with dysphagia will have difficulty eating solid foods. The compensatory treatment for this is to modify the foodstuffs successively from cutting into smaller portions through mincing to pureeing as a liquid. This too

has an economic and workload burden on carers.

IQoro training can cause patients to recover a normal swallow and return to normal, or more normal food consistencies.

Users were asked:

I have stopped needing to have modified consistency foods since I started training with IQoro.

Replies received indicate the following responses.

Ceased modified foods (I)	
Completely	45
Somewhat	103
Not at all	71
I never used them	691
Total	910

Once again, I remove those that have never used modified foodstuffs.

Ceased modified foods (II)	
Completely	45
Somewhat	103
Not at all	71
Total	219

Shown graphically, we see that a significant 68% have ceased or reduced their need for specially-modified solid foods.

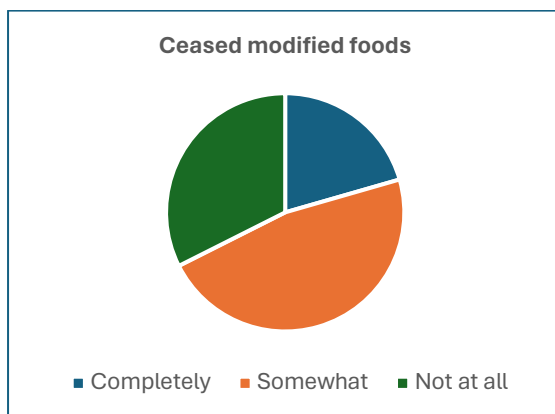


Fig.15. Ceasing or reducing modified foodstuffs. N=219

PEG removal

This question was not included in the 2019 questionnaire and hence includes only three years data.

Patients that are unable to safely and sufficiently eat or drink orally receive some or all of their nutrition via a tube. The type of tube that is inserted into the stomach is called a Percutaneous Endoscopic Gastrostomy (PEG).

It is obvious the limitations that such a feeding regime impose. So many social events involve eating or drinking with friends or family.

Training with IQoro can cause patients to recover their swallow and return to a normal oral diet even after years' of requiring PEG feeding. We asked the question:

I have had my PEG removed since training with IQoro.

PEG removal (I) - Eng	
Yes	6
No, but I can eat orally more	9
No, no change	20
I never had a PEG fitted	231
Total	266

Removing the responses for those for whom this question is not relevant we get the following picture.

PEG removal (II) - Eng	
Yes	6
No, but I can eat orally more	9
No, no change	20
Total	35

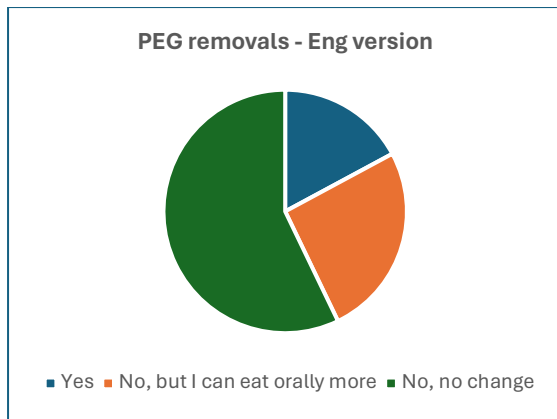


Fig.16. Removing PEG feeds. Eng language version. N=35

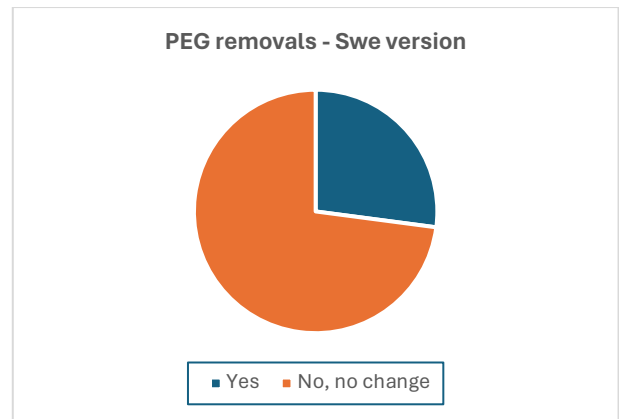


Fig.17. Removing PEG feeds. Swe language version. N=96

The numbers are small, but the impact on patients' lives is immense. IQoro has been used to treat many more PEG patients very successfully but as this is often done through a hospital setting or by a speech and language therapist we are often unaware of the patient's name or e-mail address and thus they do not figure in this survey.

Other data, not included here, show success rates of between 50 and 100% in avoiding PEG insertions, and removing existing PEGs.

The data above applies only to the English language version of the questionnaire. Due to an administrative error the Swedish language version omitted one of the three possible responses, hence their data looks slightly different.

PEG removal (III) - Swe	
Yes	20
No, no change	50
I never had a PEG fitted	573
Total	643

Removing the 'never had one' category, we have.

PEG removal (IV) - Swe	
Yes	26
No, no change	70
Total	96

Symptom improvement in detail for the ‘Top 10’ symptoms

Symptom improvement by condition

Users were asked to rate the improvements that they had seen since starting IQoro training between one and 12 months ago.

The possible responses to choose between were:

1. I am symptom-free
2. greatly improved
3. slightly improved
4. no improvement

The following tables and graphs illustrate the responses, once again I would point out that 22% of the response base had trained for less than two months.

I have restricted the analysis to the ‘Top Ten’ conditions reported before training started.

Reflux / acid reflux

Acid reflux is usually a symptom of the condition known as GORD, and most users saw an improvement in the time that they had trained up to the date of the questionnaire.

Reflux / acid reflux	
I am symptom-free	512
Greatly improved	3,181
Slightly improved	2,846
No improvement	1,308
Total	7,847

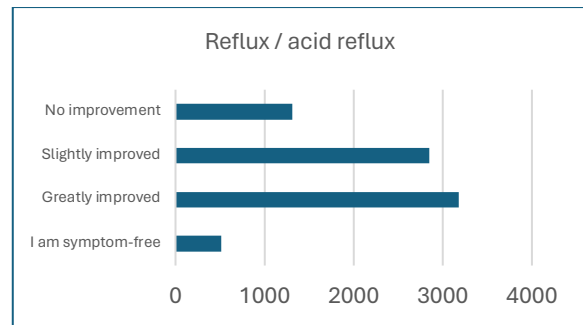


Fig. 18. Symptom improvement. Reflux / acid reflux. N= 7,847

Heartburn

Heartburn, too, is a classic symptom of GORD.

Heartburn	
I am symptom-free	416
Greatly improved	1,931
Slightly improved	1,626
No improvement	735
Total	4,708

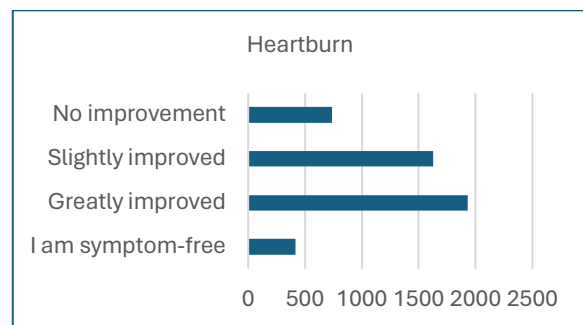


Fig. 19 Symptom improvement. Heartburn. N= 4,708

A sensation of something stuck in your throat

This symptom, known also as globus sensation, occurs when the neck of the stomach intrudes through the diaphragm into the chest cavity. In this position it compresses the oesophagus reducing its intra-abdominal length and hindering the Upper Esophageal Sphincter (UES) from opening properly. The sensation is of something being stuck in the throat that might be cured by throat clearing.

The effect of the stomach acids on the vocal cords can result in a persistent, dry, unproductive cough.

A fairly recent NHS study

<https://www.bmj.com/content/372/bmj.m4903> showed that traditional PPI medication is no more effective in treating this condition than a placebo.

Training with IQoro is shown to improve muscular strength where the esophagus passes through the diaphragm thus addressing this problem by improving the ability to keep the neck of the stomach from sliding up into the chest cavity.

A sensation of something stuck in your throat	
I am symptom-free	519
Greatly improved	1,712
Slightly improved	1,559
No improvement	771
Total	4,561

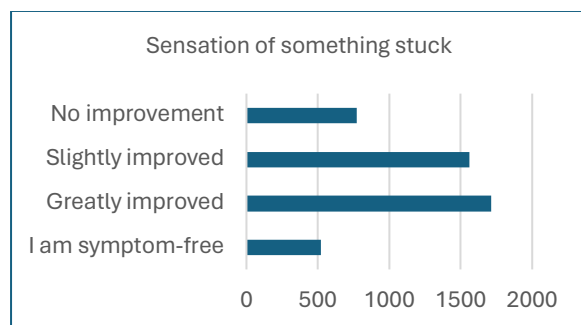


Fig. 20. Symptom improvement. Globus sensation. N=4,561

Pain in your chest or esophagus

This typically a symptom of reflux or silent reflux.

Pain in your chest or esophagus	
I am symptom-free	341
Greatly improved	1,082
Slightly improved	912
No improvement	470
Total	2,805

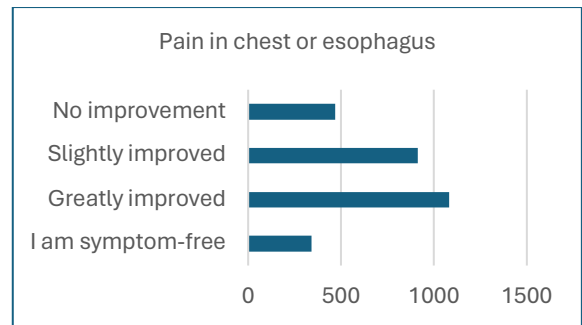


Fig. 21. Symptom improvement. Pain in chest. N=2,805

Excessive or thick phlegm

The body produces extra phlegm to protect its soft mucosa and vocal cords from damage from refluxed stomach acids.

Excessive or thick phlegm	
I am symptom-free	190
Greatly improved	1,290
Slightly improved	1,723
No improvement	1,063
Total	4,266

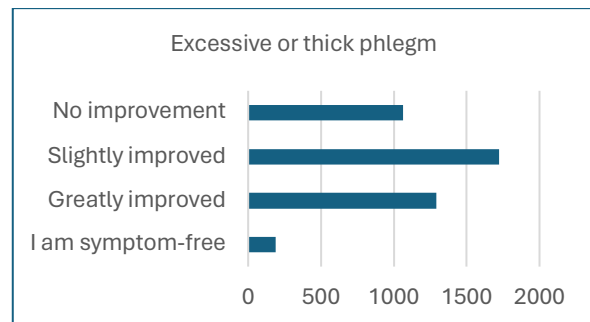


Fig. 22. Symptom improvement. Excessive phlegm. N=4,266

Difficulty in swallowing food

Conditions in this category are referred to as dysphagia. The effect of IQoro neuromuscular training is to stimulate and strengthen all 148 muscles in the swallowing chain. Oral-, pharyngeal-, and esophageal-dysphagia are all thus treated.

Difficulty in swallowing food	
I am symptom-free	128
Greatly improved	661
Slightly improved	703
No improvement	320
Total	1,812

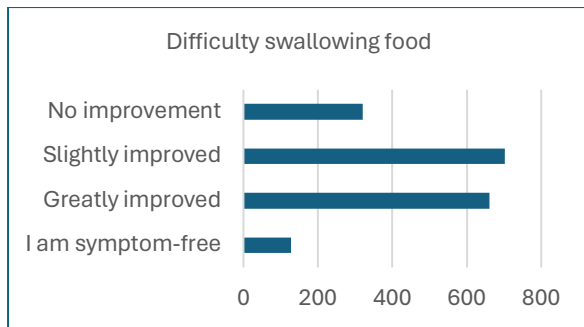


Fig. 23. Symptom improvement. Food swallowing. N=7,847

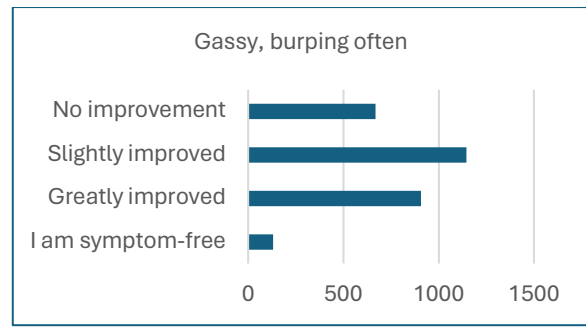


Fig. 25. Symptom improvement. Gassy, burping often. N=2,852

Dry persistent cough

See explanations in earlier paragraphs.

Dry, persistent cough	
I am symptom-free	247
Greatly improved	945
Slightly improved	972
No improvement	603
Total	2,767

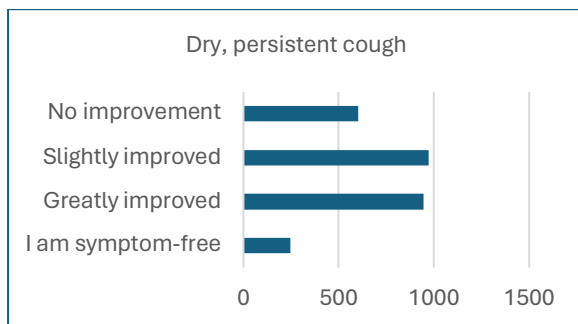


Fig. 24. Symptom improvement. Dry, persistent cough. N=2,767

Food being regurgitated

Food being regurgitated	
I am symptom-free	161
Greatly improved	432
Slightly improved	374
No improvement	171
Total	1,138

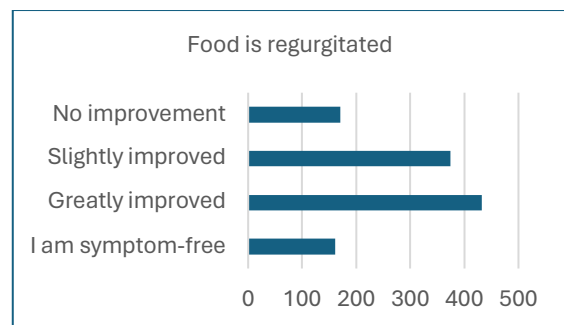


Fig. 26. Symptom improvement. Food regurgitation. N=1,348

Gassy, burping often

Gassy, burping often	
I am symptom-free	131
Greatly improved	907
Slightly improved	1,146
No improvement	668
Total	2,852

Hoarseness

Hoarseness	
I am symptom-free	217
Greatly improved	839
Slightly improved	1,136
No improvement	679
Total	2,871

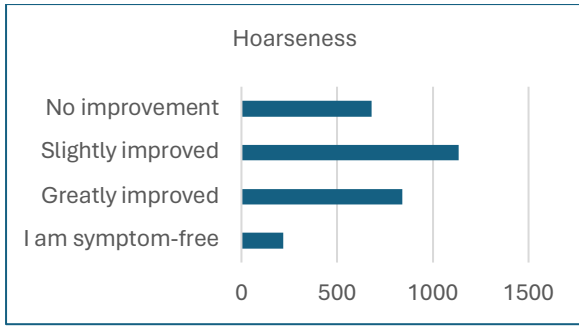


Fig. 27. Symptom improvement. Hoarseness. N=2,871

Symptom improvement and neuromuscular training - Conclusions

The following chart summarises the previous improvement data tables and makes perhaps the most important point of all.

In this chart I have listed all the symptoms that are shown above but refer to them only as #1 to #10 and grouped them by the user's success response. The detail is less important than the overall picture.

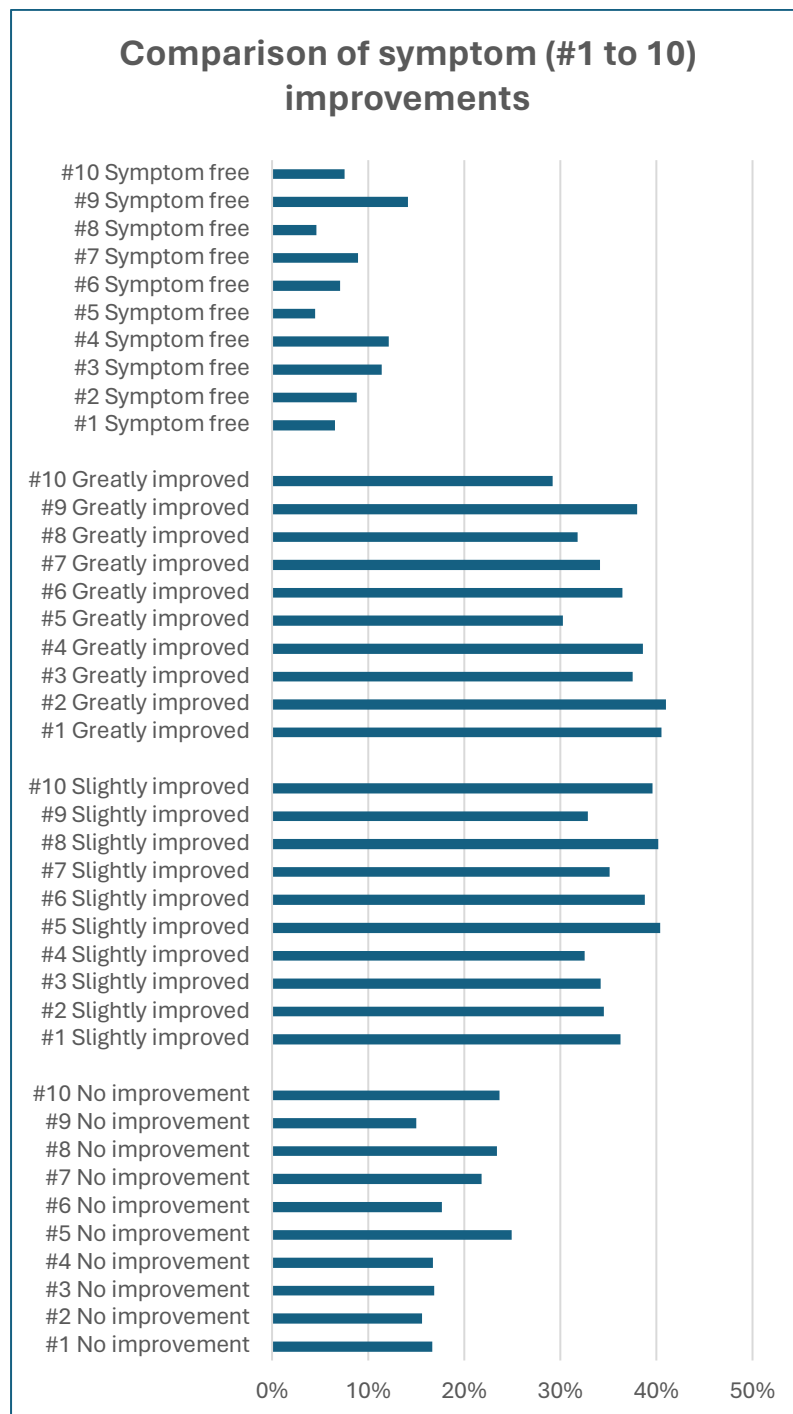


Fig. 28. Reported symptom improvement comparisons

It is clear that IQoro neuromuscular training succeeds very similarly in all 10 symptom categories. Whether completely, greatly, slightly or not improved at all, the pattern is the same across all conditions. Why this is important is that it underlines that neuromuscular training which acts on the Reticular Formation in the brainstem, activates and reinforces all 5 efferent cranial nerves and exercises and strengthens the musculature in the swallowing chain equally well. The one training action achieves all of this.

As mentioned earlier the efficacy of the device is evidenced by a range of peer-reviewed and internationally-published scientific studies. It is crucial to the understanding of what IQoro can offer to see these studies as part of a total picture as well as individually. Each of them addresses a slightly different patient conditions: oral dysphagia, pharyngeal dysphagia, impaired postural control, hiatus hernia symptoms, heartburn, reflux, and more. The sum of the studies demonstrates, as does the table above, the effectiveness of the treatment to a range of related conditions. It is not productive to consider one particular study and conclude that none of the others are reinforcing the same point. All of the studies and this customer survey data evidence the effectiveness of neuromuscular training on all the conditions that our users treat.

Patients can find themselves being referred to one or more parts of the healthcare system simultaneously or consecutively.

IQoro treatment is shown from the data in this report to be effective across a range of conditions that we traditionally view as needing separate specialities.

An approximate map of symptoms and referrals might look like this.

Ref	Symptom	Possible diagnosis relating to the part of the swallowing chain	Examples of referrals to secondary care clinicians include
1	Reflux / acid reflux	GORD	Gastroenterology, Endoscopy
2	Heartburn	GORD	Gastroenterology, Endoscopy
3	A sensation of something stuck in your throat	LPR	ENT, Endoscopy / FEES
4	Pain in your chest or esophagus	GORD	Gastroenterology, Cardiology
5	Excessive or thick phlegm	LPR	ENT, Endoscopy
6	Difficulty in swallowing food	Dysphagia	ENT, SLT, Endoscopy
7	Dry, persistent cough	LPR	ENT, Respiratory
8	Gassy, burping often	GORD	Gastroenterology
9	Food is regurgitated	GORD	Gastroenterology
10	Hoarseness	LPR	ENT, SLT, FEES

Fig. 29. Symptoms and potential referrals (approx.)