Evaluation of the Fit to Thrive Program

Aspire Fitness and Rehabilitation and the **Leukaemia Foundation of Queensland**

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Executive Summary

Over a period of 2 years, from February 2014 through to March 2016, the Leukaemia Foundation (Qld) in conjunction with Aspire Fitness and Rehabilitation and the Queensland Sports Medicine Centre conducted an individually prescribed Accredited Exercise Physiology program for people living with blood borne cancers. This program was called 'Fit to Thrive'.

The results of 'Fit to Thrive' show some impressive improvements in the fitness and the quality of life of most participating patients from the beginning to the completion of the program. Key findings were:

- A quarter (25%) of patients decreased their waist to hip ratio risk level and 36% stayed ideal or low risk.
- There was a significant increase in the average distance patients were able to walk for 6 minutes, from just under 500m at week 1 to 541m at week 12.
- There was a significant reduction in the time taken by patients on average to stand five times from a seated position, from 12 to 9 seconds.
- There was a significant increase in the average maximum distance patients were able to reach forward from 38cm to 41cm.
- The health related quality of life measures also showed great improvements: all the SF36V2 subscales and overall scores increased from week 1 to 12, and the physical component summary did so significantly. The overall FACT scores as well as the physical and functional well-being metrics also all improved significantly over the program period.
- The 6 and 12 month results seem to indicate that those improvements are lasting, with all key measures remaining higher than before the program.

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Fit to Thrive Outcome Summary

Introduction

Research is arguably increasingly showing that physical activity for cancer patients before, during, and post treatment, can improve muscular endurance, decrease symptoms of fatigue, improve balance and flexibility, increase muscle mass, and improve quality of life. A recent Survivorship study conducted by the Leukaemia Foundation Qld (LFQ) revealed that there was a shortage of resources available to recommend to patients. This lack was specifically in terms of education and services surrounding exercise and how exercise might assist their treatment during all phases of their management. This study suggested the need to develop an individually prescribed exercise program designed to meet the needs of LFQ clients and that understood the individual circumstances and guidelines for exercise prescription for this patient group.

In combination with the Leukaemia Foundation (Qld), Aspire Fitness and Rehabilitation (AFR) and the Queensland Sports Medicine Centre (QSMC) have been able to take a step toward bridging the shortage. A collaborative approach led to developing an exercise program aimed at supporting the growing base of evidence of the benefits of physical activity for people living with blood borne cancer. This project aimed to assist patients both individually and in a group setting. This allowed them to meet their individual goals, to enhance their quality of life, to provide best practice in patient care and to provide data for research into the benefits of exercise for this patient group.

People entering the study were recruited through LFQ in consultation with their treating specialists. These patients were from various sub-groups of people living with blood cancers but were universally looking to improve their functional ability. As a pilot with 142 patients, this wide-ranging group would be assessed not against each other's progress due to a wide range of inclusion criteria, rather against their own individual responses and improvements.

Clinically relevant subjective and objective measures have been recorded to assess the program's merits.

Below is a brief summary of some of the findings and superficial analysis of the measures, along with some anecdotal stories of patients' views around the program.

The impact of 'Fit to Thrive' on this cohort has been substantial. The following is a snapshot of reflection from those that completed the program;

"There is nothing like this for young people surviving Leukaemia."

The prevalence of blood borne cancer among young people means that post treatment there are very few options and a large group of people left without a suitable pathway back to their pre-diagnosis routines, as they deal with the after-effects of treatment.

"It is difficult to work long hours with my energy levels being so low and I don't have extra money to afford a gym membership."

Understandably, the lethargy experienced by patients post cancer therapy impacts on their ability to go back to work in a full time capacity. The notion of then implementing a regular exercise regime in addition to this can be daunting and often frustrating. Through individualised and appropriate progressions of exercise, Fit to Thrive has allowed participants to engage in regular physical activity in a safe and appropriate manner allowing progression.

"I have met and been able to go through the program with people who have had similar experiences."

"The group-based setting has alleviated any fears surrounding exercise and facilitated new relationships between participants."

The well-researched correlation between regular exercise and fatigue has been evident through the participants' experiences, with all reporting increased energy for activities of daily living, reduced pain and improved quality of life.

"It (the program) has been a great kick-start. Before, I had no energy; now I can get through the day without having a nap and have energy to go walking in the afternoons."

"Since joining Fit to Thrive, I have felt stronger and more able to cope with life. I have more energy and generally feel more healthy than I did in the past several years."

"Over the last twelve weeks, I've definitely seen massive improvements in my endurance and strength […]. As well, everyone at Aspire Fitness and Rehabilitation, and the Leukaemia Foundation were so lovely and supportive, which made exercising in a gym a comfortable experience (even without hair). I also loved being able to meet other people who have or had cancer, and share our experiences. Overall, Fit to Thrive is a great program and I am so thankful for all the help of everyone involved."

"Since my diagnosis and my recent stem cell transplant, the Fit to Thrive program has helped me gain physical confidence and mental focus. It has helped me get back to exercise in a guided and structured way with goals and targets specific to my needs. I would highly recommend the program to anyone that is interested in gaining back their everyday fitness or looking to start getting back into exercise or sports."

"I am impressed by the changes to my body a short training program has aided. I have never been a gym goer and was quite apprehensive in the beginning but found Aspire and Dane to be wonderful. I have more energy and get much less fatigued now and this has definitely led to a better quality of life."

About AFR and QSMC

The Queensland Sports Medicine Centre (QSMC) was established in 2001 with the aim of restoring optimal function to the sporting and general population, in the shortest possible time. Although many of their clients are elite athletes, the majority are active, everyday people in pursuit of optimal health and fitness. The Centre uses a multi-disciplinary team involving Physiotherapists, Sports Medicine Doctors and Orthopaedic Surgeons, Osteopaths, Bio-mechanists, Podiatrists, Nutritionists, Acupuncturists, Massage Therapists, Sports Psychologists and Pilates instructors to help clients overcome injury, maintain a healthy lifestyle and achieve their personal athletic goals.

In 2010 QSMC formed Aspire Fitness and Rehabilitation (AFR) as a Centre for delivery of mid to late stage rehabilitation, strength and conditioning programming, and medically specific rehabilitation services. The AFR Accredited Exercise Physiology (AEP) team specialise in the delivery of exercise, lifestyle and behavioural modification programs. These programs assist the prevention and management of chronic diseases, along with both acute and chronic injuries. Of note is they are also aimed at managing any dysfunction associated with the

mechanisms of disease including its treatment side effects. Further to this they manage many musculoskeletal disorders, post-surgical rehabilitation and Strength and Conditioning services for the general public through to elite athletes. In other words, it is designed as a Centre of Excellence providing a continuum of care with both centres combining to allow management of the acutely unwell through to return to full function.

How to read this report

This report presents the findings for week 1 and week 12 data for different patient groups who participated in the program between February 2014 to March 2016. There were a total of 167 people who took part in the program but not all completed the program and/or filled in the surveys for all time periods. Only those for whom data was recorded consistently from week 1 to week 12 are analysed in this report (n= from 106 to 119). The end of the report also contains an analysis of the long-term results of the cohort's health related quality of time 6 months (n=36) and 12 months (n=22) after the beginning of the program.

Methodology

The following statistical tests were carried out:

- To compare means of the same variable and the same population at two different points in time, the Difference-Sample or Paired Sample *t*-test was used.
- To compare means of the same variables but different populations, an Independent-Sample *t*-test was used.

When results were statistically significant, this was indicated by one to several asterisks, according to the p-value obtained: *** p<.001 ** p<.01 * p<.05

The smaller the p-value, or the higher the number of asterisks, the more significant the results are.

1 Objective Measures

There are four key objective measures that have been taken as part of the data collection for this study:

- Waist to Hip Ratio
- 6-minute Walk Test
- Sit to Stand Test
- Functional Forward Reach Test

Below is a brief explanation of each measure and of the changes that have been found in this population over the 12-week period.

Waist to Hip Ratio

Adults who store body fat around their waist are at an increased risk of developing one or more chronic diseases or conditions such as cardiovascular disease and diabetes. Measuring waist to hip ratio is a simple way of assessing weight-related health risk by measuring waist circumference in relation to hip circumference. "Abdominal obesity is increasingly recognised as a major risk factor for cardiovascular disease. Compared with body mass index (BMI), anthropometric measures of abdominal obesity including waist circumference and waist to hip ratio appear to be more strongly associated with metabolic risk factors, cardiovascular disease, and death."[1]. Abdominal obesity as measured by WC (waist circumference) and WHR (waist to hip ratio) is significantly associated with the risk of incident CVD (cardiovascular disease) events. "A 1 cm increase in WC is associated with a 2% increase in risk of future CVD

[1] *Waist circumference and waist-to-hip ratio as predictors of cardiovascular events: meta-regression analysis of prospective studies. Lawrence de Koning, Anwar T. Merchant, Janice Pogue, Sonia S. Anand. European Heart Journal Apr 2007, 28 (7) 850-856; DOI: 10.1093/eurheartj/ehm026*

and a 0.01 increase in WHR is associated with a 5% increase in risk.". Conversely, a reduction decreases those risks of future CVD and the associated risks.

Figure 1 Health Risk Categories based on Waist to Hip Ratio

Health Risk Based on WHR	Male	Female
Ideal – Very low Risk	Close to 0.9	Close to 0.7
Low Risk	0.95 or below	0.80 or below
Moderate Risk	0.96 to 1.0	0.81 to 0.85
High Risk	1.0+	0.85+

In week 1, out of 119 patients, 15% had an ideal waist to hip ratio, 39% presented a low risk, 17% presented a moderate risk and 29% presented a high risk. At the completion of the program, the proportion of patients with an ideal ratio had increased to 21% and the proportion of high risk patient had decreased to 26%.

Majority of those who had an ideal waist to hip ratio at week 1 (78%) managed to maintain it at week 12. There were some improvements that should be highlighted: 20% of those with a low risk and 10% of those with a moderate risk at week 1 presented an ideal profile at week 12. Nearly half (45%) of those with moderate risk at week 1 presented a low risk at week 12. Almost a third (29%) of those with a high risk at week 1 decreased their risk profile to either moderate (20%) or low (9%).

Figure 2 Waist to Hip Ratio in Week 1 and 12

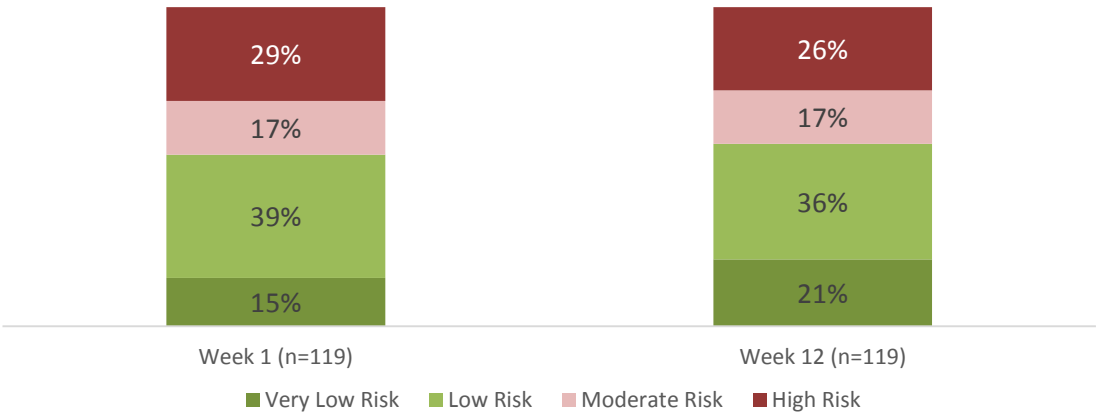
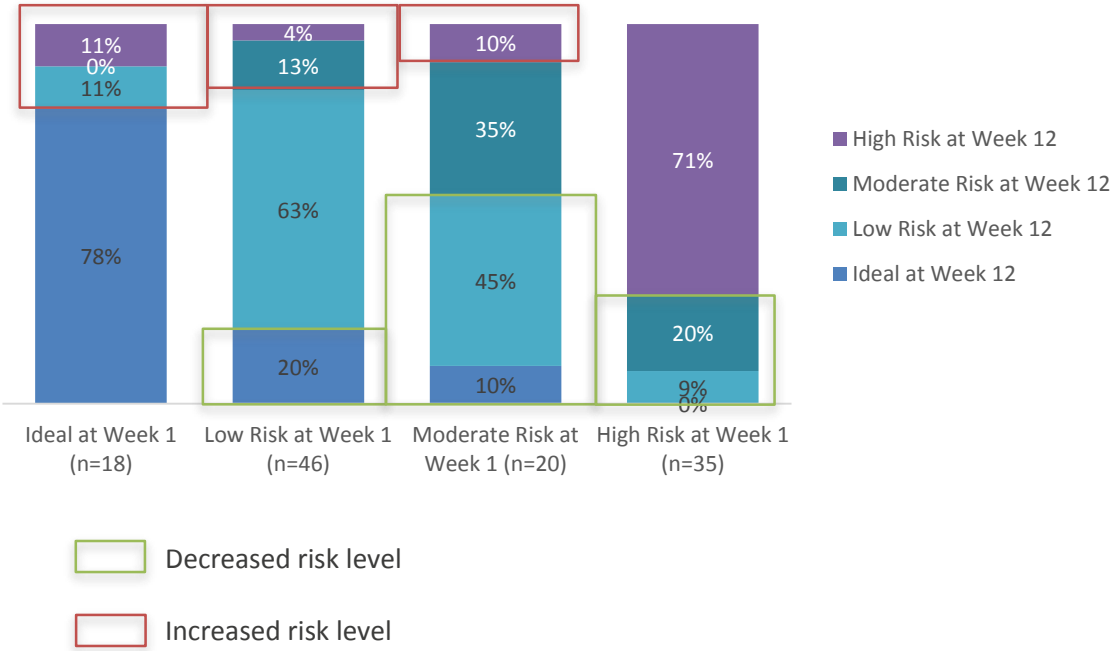


Figure 3 Waist to Hip Ratio Risk Profile from Week 1 to Week 12



The 6-minute Walk Test

The 6-minute walk test measures the distance an individual is able to walk over a total of 6 minutes on a hard, flat surface. This is a performance-based measure of functional exercise capacity.

The patient cohort (n=113) significantly increased their average walking distance by 45m from 496m to 541m over the 12 weeks (p<.001).

Majority (78%) of the patient cohort increased their walking distance by an average of 69 metres. 17% of the patients decreased their walking distance by an average of 52m and 5% maintained the same distance.

The maximum increase in the walking distance was achieved by a female patient who increased it by nearly 200m from 343m to 542m.

Figure 4 6-minute Walk Test Average Distance Comparison at Week 1 and Week 12

Base n = 113	Week 1	Week 12
Walking Distance (m)	496	541***

***p<.001

Patients who were undertaking treatments against cancer, such as chemotherapy, radiotherapy or other treatments were experiencing a significantly higher increase on average between week 1 and 12 (54m compared to 26m for patients with no treatment).

Sit to Stand Test

The sit to stand test assesses functional lower limb strength. This is measured by time taken to stand five times from a seated position.

This patient group (n=114) improved in lower limb strength significantly over the study period, shifting from an average of 12.1sec test time to 9. 4sec, which represents a significant reduction of 2.7sec (p<.001).

There were 86% of the patient cohort who improved in lower limb strength by 3.3sec on average, 1% who maintained their time and 13% who had a higher time score at week 12 than week 1 by 1.1sec on average.

Figure 5 Sit to Stand Test Average Time Comparison at Week 1 and Week 12

Base n = 114	Week 1	Week 12
Sit to Stand (sec)	12.1	9.4***

***p<.001

Functional Forward Reach Test

The Functional Forward Reach test assesses an individuals' balance and stability by measuring the maximum distance the individual can reach forward while standing in a fixed position.

The average maximum distance patients were able to reach at week 12 had improved by 3.1cm to reach 41.0cm, which was significantly higher than the average score at week 1 (p<.01).

Over two-thirds (69%) of the Fit to Thrive cohort (n=116) improved their functional forward reach, increasing it on average by 6.9cm from week 1 to week 12, while 2% did not see any change over the period and 29% experienced a decrease of 5.5cm on average.

Figure 6 Functional Reach Test Average Distance Comparison at Week 1 and Week 12

Base n = 116	Week 1	Week 12
Functional Reach (cm)	37.9	41.0**

**p<.01

Patients who were undertaking treatments against cancer, such as chemotherapy, radiotherapy or other treatments experienced a significantly higher increase on average (5.0cm compared to 0.7cm for patients with no treatment).

2 Subjective Measures

Health related Quality of Life

Health is not just the absence of disease, it is complete physical, social, and mental wellbeing. Using quality of life measures ensures that treatment and evaluation focus on the patient rather than the disease. The measures are useful clinically, as well as to assess the improvement in quality of life. The SF36v2 questionnaire[2] is a scientifically validated and reliable measure of health related quality of life and reports on 8 measures in the domains of physical and mental well-being. It also identifies an 'at risk' population.

The scores presented below are standardised using norm-based scoring (NBS). NBS applies a linear T-score transformation (Mean = 50, SD=10), which makes it possible to meaningfully compare scores for the eight-scale profile and the physical and mental summary measures across samples[3].

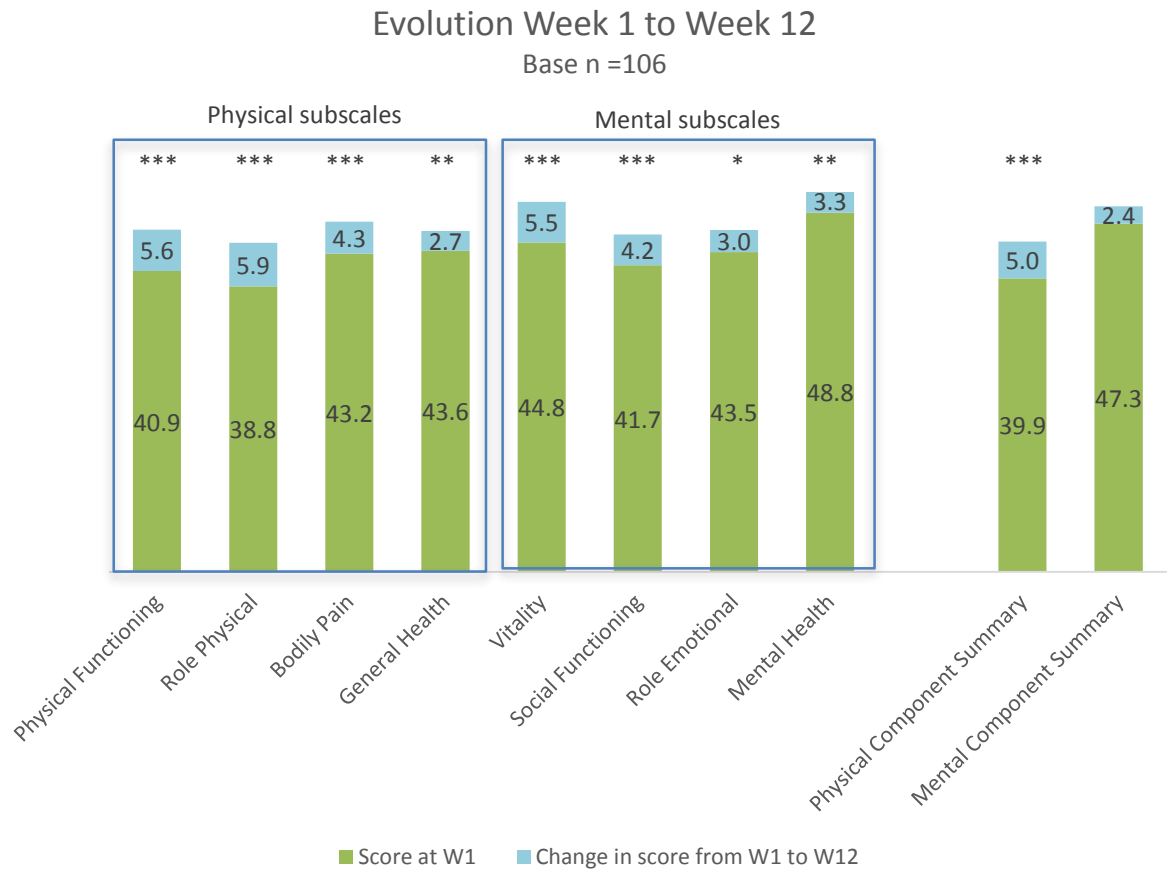
On average, across the patient cohort (n=106), all the SF36V2 subscales, both physical and mental, have increased significantly between week 1 and week 12.

As a result, the overall summary measures improved as well, and the physical component did so significantly ($p<.001$).

[2] It should be noted that the questionnaire used had a 6-point scale for Q6, which was later converted to a 5-point scale by merging the 2 middle-point answers ('mild' and 'moderate') in order to fit the standard SF36V2 template.

[3] https://www.qualitymetric.com/Portals/0/Uploads/Documents/Public/Norm-based%20Scoring%20(NBS).pdf

Figure 7 SF36V2 Average Score Evolution between Week 1 and Week 12



*** p<.001 ** p<.01 * p<.05

Gender plays a role in the changes witnessed during the program: female patients experienced significantly higher increases in Physical Functioning (7.5 vs 3.9 for males), Role Physical (8.3 vs 3.7), Vitality (8.2 vs 3.1), Social Functioning (6.7 vs 1.8), and the Physical Component Summary (7.3 vs 2.8). In addition, patients who had undertaken cancer treatments such as chemotherapy, radiotherapy, had significantly higher increases on average in their Physical Functioning (7.4 vs 0.7) and their Physical Component Summary (6.1 vs 1.8). In addition, those who experienced persistent side effects from their treatment had on average higher increases in their Mental Component Summary (2.6 vs -12.5).

Those who did not consume any alcohol had significantly higher increases in their Social Functioning (7.6) than those who had at least one alcoholic drink per week (1.3) and particularly than those who had more than 3 drinks weekly (-2.1).

Changes in Social Functioning and Mental Health were also influenced by the existing level of activity patients had at the beginning of the program. Interestingly, those who described themselves as inactive at week 1 had on average significantly higher increases in their Social Functioning compared to those who were already active (6.9 vs 4.1) and in their Mental Health (5.5 vs 1.1).

Out of the 106 participants, 75% improved their Physical Component Summary and 64% increased their Mental Component Summary. The highest proportions of patients who increased their score occurred for the Physical Functioning (74%), Role Physical (74%) and Vitality (60%). A remarkable 60% also recorded an improvement in their Mental Health.

Figure 8 SF36V2 Scores Evolution Between Week 1 and Week 12

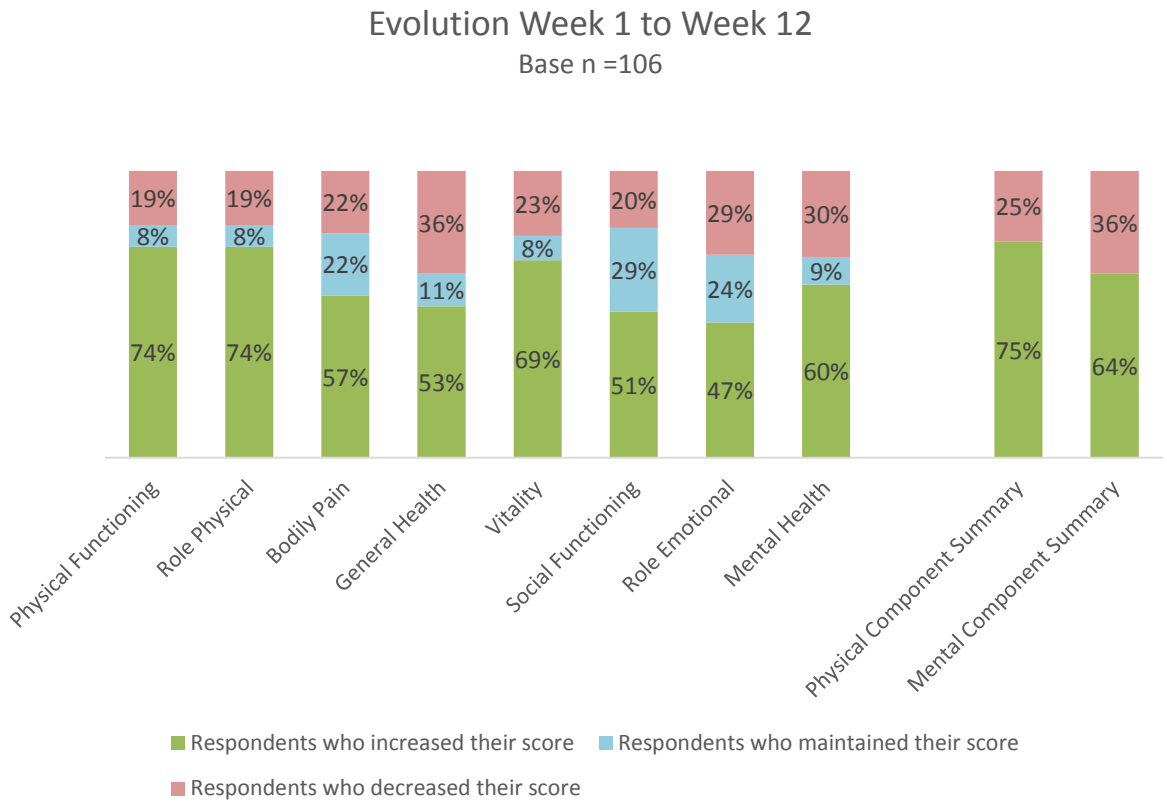


Figure 9 SF36V2 Average Score Evolution between Week 1 and Week 12

Average evolution week 1 to 12 (base n=106)	Physical Functioning	Role Physical	Bodily Pain	General Health	Vitality	Social Functioning	Role Emotional	Mental Health
Total patients	+18%	+21%	+14%	+10%	+16%	+17%	+13%	+12%
Patients who increased	+28%	+34%	+31%	+28%	+29%	+44%	+43%	+28%
Patients who decreased	-15%	-21%	-18%	-14%	-18%	-26%	-23%	-17%

Average evolution week 1 to 12 (base n = 106)	**Physical Component Summary**	**Mental Component Summary**
Total patients	**+15%**	**+10%**
Patients who increased	**+25%**	**+26%**
Patients who decreased	**-15%**	**-19%**

FACIT and FACT - LEU

The Functional Assessment of Chronic Illness Therapy (FACIT) questionnaire measures health-related quality of life for people with chronic illness and is commonly used in national and international research settings. Comprised within the FACIT are measures for Physical Well-Being, Social/Family Well-Being, Emotional Well-Being, and Functional Well-Being. The FACT-LEU is a subset of the FACIT, and has been measured to be a reliable and valid measure for health related quality of life in people with leukaemia.

All scores have increased, which indicates a positive improvement in the quality of life of the patients. In particular, the physical and functional well-being measures and the Leukaemia subscale saw a significant increase (p<.001). The three overall FACT scores all improved significantly.

Figure 10 FACT Average Score Comparison at Week 1 and Week 12

Base n = 106	PWB	SWB	EWB	FWB	LEUS	FACT Leukaemia TOI	FACT-G Total score	FACT Leukaemia Total score
Week 1	19.22	21.20	18.49	16.33	47.62	83.18	75.25	122.87
Week 12	21.22	21.57	19.39	18.56	51.55	91.33	80.74	132.29
Sig.	***			***	***	***	***	***

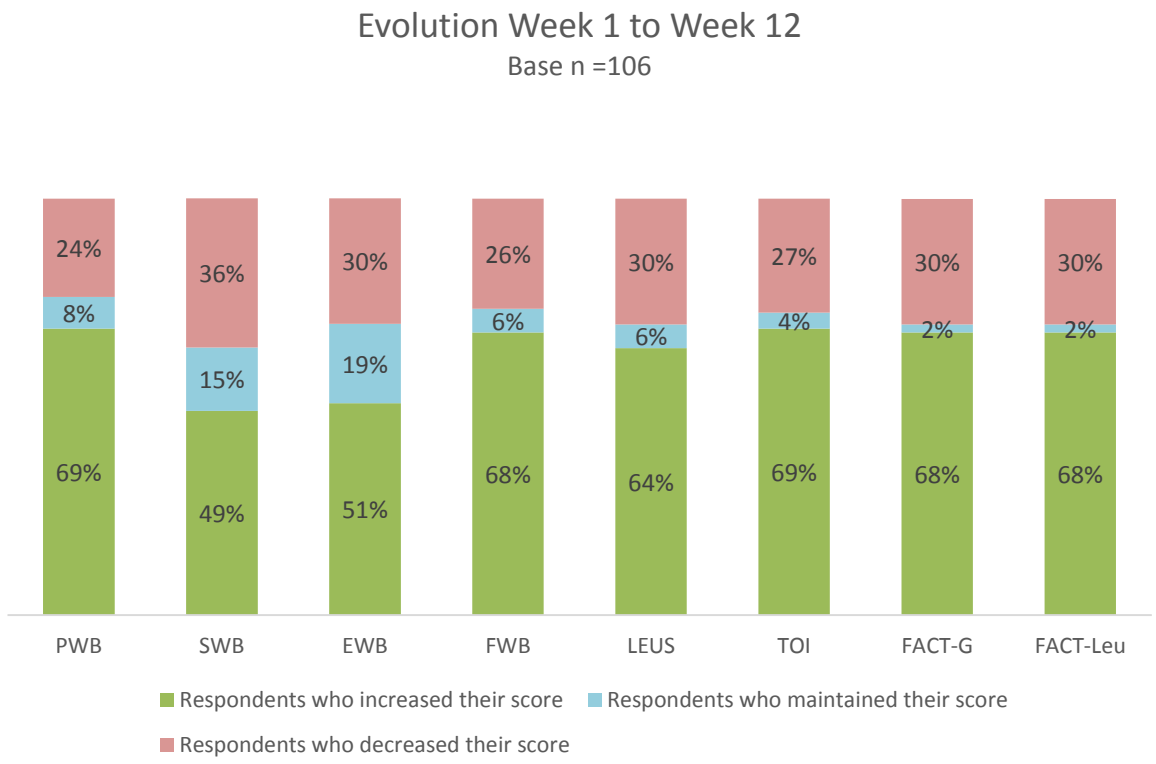
*** p<.001

Interestingly, patients with myeloma had significantly higher average increases in their Social Well-being (2.5) compared to other cancer types (-1.0 for leukaemias, -0.4 for lymphomas, 1.2 for MPN, -0.8 for MDS and 2.1 for related blood disorders). Those who had had cancer-related surgery also had significantly higher increases on average in their LEUS score (7.0) compared to those who did not have surgery (2.2).

Patients who were past smokers had significantly lower increases on average compared to those who had never smoked in their FACT Leukaemia TOI (1.6 vs 9.4) and their LEUS scores (0.4 vs 4.6). Similarly, those who consumed more than 3 alcoholic drinks per week had significantly lower changes than those who had 2 or less in their FACT-G (-1.3 vs 7.9) and their Functional well-being (-1.3 vs 3.5).

Some two-thirds (68%) of participants have experienced an increase in their overall FACT-LEU score from week 1 to week 12. In particular, 69% of the cohort saw an increase in their Physical Well-being, 68% in their Functional Well-being, 51% in their Emotional Well-being and nearly half (49%) in their Social Well-being.

Figure 11 FACT Average Score Evolution Split between Week 1 and Week 12

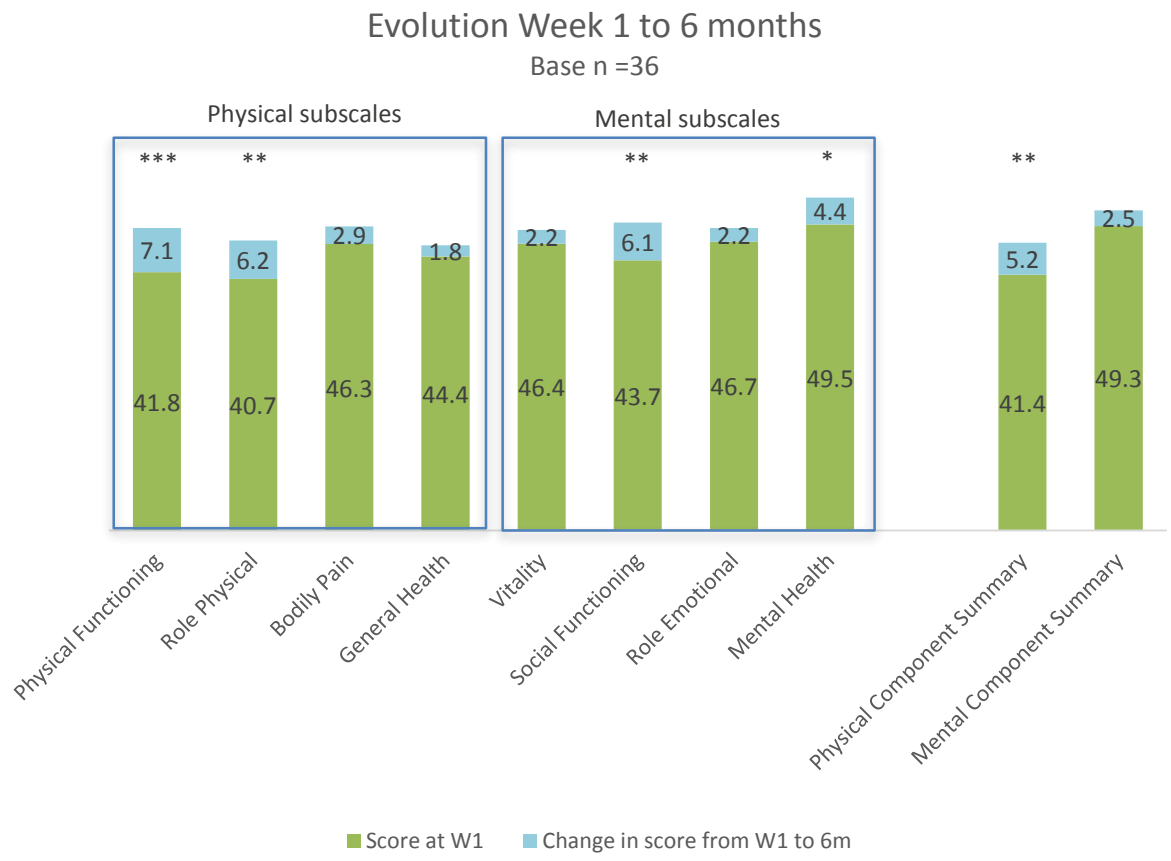


Long-term Impact

Review questionnaires were sent out to the cohorts that have passed the 6 and 12 month milestones post intervention to assess their QoL using the SF36v2 and FACT-LEU outcome scores that were used in the original study.

All measures of the SF36V2 still show an improvement on average across the patient cohort (n=36). In particular, Physical Functioning has increased significantly (p<.001), as well as Role Physical and Social Functioning (p<.01), and Mental Health (p<.05). The Physical Component Summary has also increased significantly from the beginning of the program until the 6-month mark (p<.01).

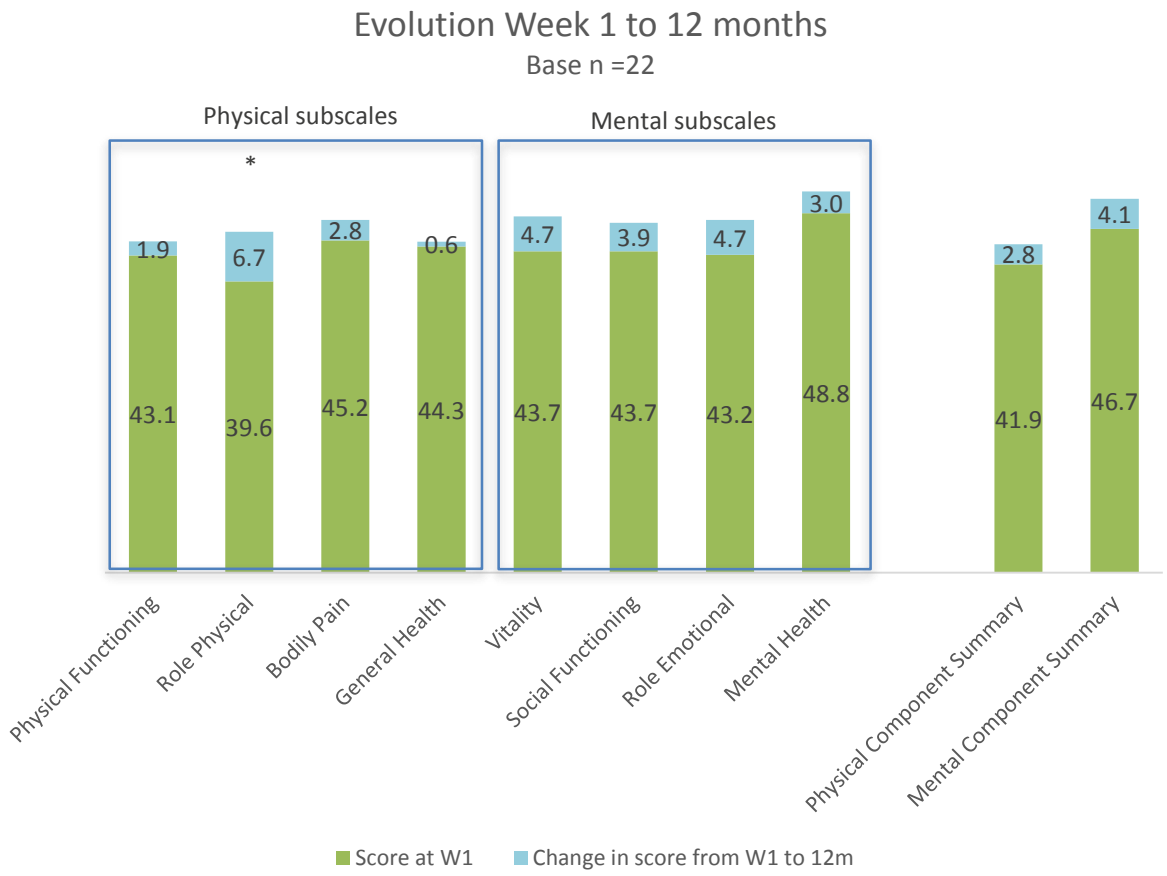
Figure 12 SF36V2 Average Score Evolution between Week 1 and 6 months



*** p<.001 ** p<.01 * p<.05

The average results after 12 months still show an improvement on all measures compared to the baseline, although only one of the SF36V2 increases, the Role Physical, is statistically significant.

Figure 13 SF36V2 Average Score Evolution between Week 1 and 12 months



*** p<.001 ** p<.01 * p<.05

The FACT results were also positive with all measures showing an improvement an average across the cohort (n=36), including two measures: functional well-being and the overall FACT Leukaemia Trial Outcome Index which were significant (p<.05).

Figure 14 FACT Average Score Comparison between Week 1 and 6 months

Base n = 36	PWB	SWB	EWB	FWB	LEUS	FACT Leukaemia TOI	FACT-G Total score	FACT Leukaemia Total score
Week 1	20.25	21.97	18.92	17.03	48.36	85.64	78.16	126.52
6 months	21.83	22.69	19.69	19.67	51.03	92.53	83.88	134.91
Sig.				*		*		

*** p<.001 ** p<.01 * p<.05

At the 12-month mark, all FACT measures were still higher on average than at the beginning of the program, however the changes are not statistically significant.

Figure 15 FACT Average Score Comparison between Week 1 and 12 months

Base n = 22	PWB	SWB	EWB	FWB	LEUS	FACT Leukaemia TOI	FACT-G Total score	FACT Leukaemia Total score
W1	19.24	20.37	18.22	17.05	47.82	84.11	74.89	122.70
12 months	20.36	21.56	19.32	18.82	48.68	87.86	80.06	128.74
Sig.								

*** p<.001 ** p<.01 * p<.05

Conclusion

The Fit to Thrive program has been a powerfully positive experience for its participants. Based on the accumulated data and growing body of feedback, the program has been able to deliver an individualised approach to rehabilitation in a group setting with statistically significant, dramatic impacts on functional strength and endurance, fatigue and psycho-social measures.

These remarkable improvements are beginning to demonstrate relevant statistical power despite the varying factors such as differences in blood borne cancers, stages of cancer and individual backgrounds of the individual subjects in the study.

In light of this, the outcomes of this pilot study into exercise based interventions for patients undergoing treatment may begin to act as a scientifically relevant way to demonstrate the positive outcomes for fatigue tolerance, self-efficacy and psycho-social measures in subjects with blood borne cancer.

As the program evolves and continues to accumulate data, refined recommendations will develop into exercise rehabilitation as an adjunct therapy to traditional blood borne cancer treatments.

Appendix

Sample Profile

The sample was constituted as indicated by the below tables:

Gender	**n**	**%**
Female	78	47%
Male	89	53%
Total	**167**	

Cancer Type	**n**	**%**
Leukaemias	43	30%
Lymphomas	50	35%
Myeloma	38	28%
Myeloproliferative Neoplasms (MPN)	5	4%
Myelodysplastic Syndrome (MDS)	3	2%
Related Blood Disorders	3	2%
Total	**142**	

Cancer Related Surgery	n	%
Yes	50	34%
No	97	66%
Other Treatment		
Yes	105	71%
No	42	29%
Treatment ongoing		
Yes	41	39%
No	63	61%
Experiencing persistent side effects from this treatment		
Yes	34	81%
No	8	19%
Taking medications for cancer or cancer complications		
Yes	92	63%
No	53	37%

Smoking History	n	%
Never	103	70%
Past Smoker	33	22%
Current Smoker	11	8%

Number of alcoholic drinks consumed per week		
0	71	48%
1-2	38	26%
3-5	22	15%
More than 5	16	11%

Current activity level	n	%
Inactive	69	47%
Active	78	53%
Average activity session length		
<30 minutes	60	47%
30-60 minutes	56	43%
>= 60 minutes	13	10%
Weekly frequency of exercise		
0	29	24%
1-3	56	46%
4-5	20	17%
5 or more	16	13%