

Improving clinical outcome in patients with intestinal failure using individualised nutritional advice

Alison Culkin^{1,2,3}, Simon M. Gabe², Angela M. Madden^{3,4}

¹ Department of Nutrition and Dietetics, ²Lennard-Jones Intestinal Failure Unit, St Mark's Hospital, Harrow, UK. ³Department of Health and Human Sciences, London Metropolitan University, London, UK. ⁴ School of Health and Emergency Professions, University of Hertfordshire, Hatfield, UK.

Contact details for corresponding author

Alison Culkin, Department of Nutrition and Dietetics, Northwick Park and St Mark's Hospital, Watford Road, Harrow, Middlesex, HA1 3UJ, UK. Telephone 0208 8692666, fax 0208 8692659, email Alison.culkin@nwlh.nhs.uk

Dr Simon M.Gabe, Lennard-Jones Intestinal Failure Unit, St Mark's Hospital, Harrow, HA1 3UJ, UK. Telephone 0208235 4177, fax 0208 2354001, email simon.gabe@nwlh.nhs.uk

Dr Angela M. Madden, University of Hertfordshire, College Lane, Hatfield, Hertfordshire, AL10 9AB, UK. Telephone 01707 281385, fax 01707 284977, email a.madden@herts.ac.uk

Abstract

Background

Patients with intestinal failure are required to adhere to a complex regimen. Written information may increase knowledge leading to improvements in clinical outcomes. The aim was to evaluate the effectiveness of nutrition advice incorporating the use of a booklet.

Methods

Patients completed questionnaires evaluating knowledge of the regime and quality of life and kept a diet and gastrointestinal output diary. The diary was assessed and they were given the booklet with a verbal explanation tailored to individual requirements. The booklet explained the causes of intestinal failure, diet and fluid recommendations in relation to intestinal anatomy, information on medications and long term monitoring. Patients were reassessed at their next appointment using the same tools. The primary endpoint was an improvement in knowledge. Secondary endpoints were an improvement in oral nutritional intake, nutritional status, quality of life and the content of home parenteral nutrition.

Results

Forty-eight patients completed the study. Knowledge improved significantly after dietetic intervention in association with the provision of the booklet ($P < 0.001$). Oral energy ($P = 0.04$) and fat ($P = 0.003$) intake increased with an improvement in body mass index ($P = 0.02$). Patients on home parenteral nutrition showed a reduction in parenteral energy ($P = 0.02$), nitrogen ($P = 0.003$), volume ($P = 0.02$) and frequency ($P = 0.003$).

Conclusion

A booklet for patients with intestinal failure in conjunction with personalised dietary counselling improves knowledge and clinical outcomes.

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Introduction

Chronic intestinal failure (CIF) occurs when the function of most of the small intestine is lost either through extensive resection, for example in Crohn's disease or mesenteric infarction, or as a result of severe chronic conditions such as radiation enteritis, intestinal fistula formation or scleroderma. All patients with CIF need to modify their oral intake in order to avoid dehydration due to severe diarrhoea or unmanageable output from a stoma or fistula. By optimising nutritional intake and maximally utilising the remaining intestine, some patients can maintain or improve their nutritional status and may even be able to reduce their dependency on home parenteral nutrition (HPN) (Jeppesen and Mortensen, 2001). The importance of education in CIF patients has been emphasized by DiBaise *et al* (2006) and is considered the optimum strategy to deliver a good understanding of the rationale underpinning dietary and pharmacological treatments. They recommended the provision of written information in combination with educational consultations by a multidisciplinary team experienced in treating these patients. In particular, they concluded that successful weaning from parenteral nutrition requires a highly motivated patient, willing and able to comply with the burden of dietary modifications and fluid restrictions. A lack of understanding may lead to sub-optimum management and this, potentially, has clinical implications. For example, the ability to recognise and respond appropriately to increased intestinal output and dehydration by adjusting the doses of anti-diarrhoeal medication and administering additional intravenous saline is vital. Increasing knowledge is an important step in empowering patients to self-manage and reduce their dependency on healthcare professionals (NICE 2006). However, this may be the first of many steps required in the complex process of helping patients to adjust to living with a chronic condition which requires adherence to complex medical and dietetic interventions. Previous studies have identified that patients on HPN have expressed an interest in receiving more information about their condition and treatment (Malone 1989). Several small studies have investigated the optimum diet for patients with CIF and their findings have been used as a basis for dietary management

(Culkin 2007). Many other studies have focused on the most effective way to communicate dietary and therapeutic information to patients although, to date, few have investigated this in CIF. O'Connor et al (1988) investigated the knowledge of patients receiving HPN and found that 18% were unable to name any components of their feed and only 50% knew that HPN contained the equivalent of protein. They stated that by providing written information to patients on HPN in order to increase their knowledge may improve compliance with HPN and reduce feelings of dependency on healthcare professionals. However, these findings were not related to an intervention or to clinical outcome.

The aim of the study was to evaluate an intervention based on personalised nutrition advice incorporating the use of an information booklet for patients with CIF. The primary endpoint was an improvement in patients' knowledge and secondary endpoints were an improvement in oral intake, nutritional status, quality of life and content, volume and frequency of HPN infusion.

Materials and methods

Adult out-patients with CIF were recruited to the study which was approved by the Local Ethics Committee. All patients underwent an initial assessment described below, immediately prior to and during an out-patient appointment (Figure 1). Patients completed questionnaires evaluating their knowledge of the CIF regimen and quality of life and kept a 3-day diet and gastrointestinal output diary before attending. At their appointment, they were given an information booklet with a verbal explanation by a dietitian, tailored to their individual requirements, depending on their intestinal anatomy and current oral intake. The booklet explained the physiology of intestinal failure and provided information on the most appropriate oral food and fluid intake, optimum use of medications to reduce acid production and slow intestinal transit and long term monitoring. Patients were reassessed at their next routine appointment using the same tools as at the initial assessment. It was considered unethical to withhold information from patients and, therefore, no control group was included.

Patients were excluded if they were unable to understand English or complete written records, had intestinal obstruction or underwent surgery between appointments, required additional dietary modifications i.e. renal failure or diabetes, or had previously received the booklet.

Assessments

Knowledge questionnaire

A questionnaire was devised to assess knowledge of the intestinal failure regimen. Patients completed the questionnaire before receiving the booklet and at re-assessment, in the presence of the dietitian to ensure that they did not refer to it. Patients received one point for a correct answer but if a question was answered incorrectly, one point was deducted from their final percentage and so the questionnaire was negatively marked with a potential score expressed between -100% and +100%.

Dietary intake and gastrointestinal output

Patients kept a diet diary recording food and fluid intake over a 3-day period prior to each appointment. The diaries were reviewed by the dietitian and then the description of food quantity was converted to weight using a photographic atlas of food portion sizes (Nelson *et al.*, 1997). A computerized nutrient analysis program was used to calculate the energy, protein, fat, carbohydrate and fibre intake (CompEat, Carlson Bengston Consultants Limited, London).

Over the same 3-day period, a diary of gastrointestinal output was also recorded. For patients with their bowel in continuity, this was assessed for volume and consistency using the King's Stool Chart, which incorporates a scoring system (Whelan *et al.*, 2004). For patients with a stoma, assessment was undertaken using a specially devised procedure incorporating the Bristol stool scale (O'Donnell *et al.*, 1990). To validate this, a separate group of inpatients with CIF were asked to estimate when their stoma bag was $\frac{1}{4}$, $\frac{1}{3}$, $\frac{1}{2}$, $\frac{2}{3}$, and $\frac{3}{4}$ full and then to empty this volume into a measuring jug. The spread of responses was examined by calculating the coefficient of variation and repeatability assessed by calculating the intra-class correlation. The analysis was performed separately on four patients with a jejunostomy and four with an ileostomy. An overall score for stoma output was then calculated by multiplying the consistency according to the Bristol stool form scale with the amount estimated by the patient (i.e. $\frac{1}{2}$ full at scale 3 = 1.5 score). A reduction in score between the two time points thus indicated an improvement in consistency and/or a decrease in volume.

Assessment of nutritional status

Weight and height were measured and body mass index (BMI) calculated. The presence of ascites and/or oedema was noted. Mid-arm circumference and tricep skin fold thickness (TST) were measured using standard techniques and mid-arm muscle circumference (MAMC) calculated (Gurney & Jelliffe, 1973). All measurements were completed by a single observer as previously described (Madden and Morgan, 1999).

Quality of life questionnaires

The SF-36 and the EQ-5D questionnaires were used to assess quality of life (Ware, 1993; Dolan *et al.*, 1995). Both questionnaires are designed for self-completion and have been used to assess quality of life of patients on HPN (Richards and Irving, 1997).

Home parenteral nutrition

The content, volume and frequency of infusions of prescribed HPN were recorded at the initial and follow-up appointments.

Booklet evaluation

All patients were asked to subjectively evaluate the usefulness and readability of the booklet using a simple devised questionnaire which allowed them to return anonymous responses.

Statistics

A 2-sided sample size calculation indicated that 48 patients were required to complete the study in order to detect an increase in knowledge from 40 to 60% based on 5% significance, 90% power. The difference between the variables before and after the booklet was analysed using paired t-tests if data were normally distributed and Wilcoxon-matched pairs test if the data were not normally distributed. Sub-group analyses were performed on patients receiving HPN (n=33). All analyses were undertaken using Stata (version 9.2, StataCorp, 2006, Texas, USA).

Results

One hundred and thirty-eight patients were screened for the study, 55 consented to take part and 48 completed the study including 33 receiving HPN (Table 1). The seven patients failed to complete the study were not anatomically or nutritionally different from those who completed (Figure 1).

Knowledge questionnaire

Patients' mean knowledge score improved significantly after intervention with the booklet ($P < 0.001$) (Table 2).

Dietary intake

Forty-three patients (90%) completed 3-day diet diaries before and after receiving the booklet. Mean oral energy ($P=0.04$) and fat ($P=0.003$) intake significantly increased in all patients with similar results in the sub-group of patients receiving HPN (Table 2).

Gastrointestinal output

Results of the output validation are shown in Table 3. The coefficient of variation for measuring output in patients with a jejunostomy increased with an increasing quantity of fluid with a small amount of within-subject variability. By contrast in the ileostomy subjects, the coefficient of variation decreased for larger quantities. There was good intra-class correlation for all volumes except $\frac{3}{4}$ full. Therefore, data from the output diaries need to be interpreted with caution. Although 43 patients provided output diaries, full data were only available for 38. Of these, five patients recorded volume in millilitres of gastrointestinal output so a score was not assigned and these were analysed separately. Paired data analysis was, therefore, carried out on 33 patients. There was no significant increase in gastrointestinal output measured using either method (Table 2).

Nutritional status

None of the patients studied had ascites or oedema at either assessment. Although not clinically beneficial, there was a statistically significant increase in mean BMI ($P = 0.02$) and there were no statistically significant changes in mean TST or MAMC (Table 2).

Quality of life

There was no significant improvement in any of the variables measured when all patients were analysed together (Table 2). In patients on HPN, an improvement in the EQ-5D VAS ($P = 0.001$) and index ($P = 0.007$) with a trend towards an improvement in the health perception aspect of the SF-36 ($P=0.06$) was observed (Table 2). Patients who reduced the frequency of infusions showed an improvement in EQ-5D index ($P=0.006$) and the physical functioning aspect of the SF-36 ($P=0.03$) compared to those who maintained the frequency of infusions. Differences between those dependent on and independent of HPN were observed with changes in the EQ-5D VAS ($P=0.01$) and index ($P=0.01$), and the physical functioning ($P=0.03$), role-physical ($P=0.03$), mental health ($P=0.02$), bodily pain ($P=0.02$) and energy/fatigue ($P<0.001$) aspects of the SF-36 with patients on HPN improving more than those not on HPN (Table 4).

HPN requirements

A significant reduction in mean parenteral energy ($P=0.02$), frequency of infusions ($P=0.003$) and volume ($P=0.02$) prescribed was observed. In addition, there was a significant reduction in the median parenteral nitrogen ($P=0.003$) prescription. There was a trend for a reduction in mean glucose ($P=0.05$) but this did not reach statistical significance (Table 2).

Patients' evaluation of the booklet

Forty-six patients evaluated the booklet. Overall, 74% considered the booklet very useful and 76% found it very easy to understand. Seventy-eight percent of patients stated that they had learnt something new and 96% of patients that had previously received other information on CIF, rated the booklet as better or much better.

Discussion

This is the first study in patients with CIF to demonstrate that personalised nutritional advice, tailored to specific requirements in conjunction with an information booklet, significantly improves knowledge of the CIF regimen.

The importance of education in CIF patients has been reviewed by DiBaise *et al* (2006) and is considered the optimum strategy to deliver a good understanding of the rationale underpinning dietary and pharmacological treatments. They recommended the provision of written information in combination with educational consultations by a multidisciplinary team experienced in treating these patients. In particular, they concluded that successful weaning from parenteral nutrition requires a highly motivated patient, willing and able to comply with the burden of dietary modifications and fluid restrictions. A lack of understanding may lead to sub-optimum management and this, potentially, has clinical implications. Increasing knowledge is an important step in empowering patients to self-manage and reduce their dependency on healthcare professionals. However, it may be the first of many steps required in the complex process of helping patients to adjust to living with a chronic condition which requires adherence to complex medical and dietetic interventions.

Although findings in this study show a positive effect of the intervention on knowledge, it would be incorrect to assume that the relationship between knowledge and adherence to an optimum management regimen is straightforward. Indeed, the issues affecting patient adherence to medical and dietetic regimens are multi-factorial (Figure 2). The exact role played by knowledge in relation to regime adherence was not investigated specifically in the present study but, instead, surrogate markers of its effect were used as measures of adherence. Direct measures of adherence could have been used, such as accurate measurement of urine and gastrointestinal output volume, but these have inherent difficulties in an outpatient setting.

The evaluation of nutritional status as an outcome measure is clinically useful but accompanied by difficulties both in methodology and interpretation (Gibson 2005). One of the aims of HPN is the attainment of an acceptable nutritional status and this becomes a particular focus when patients are weaned from HPN so that as infusions are reduced, their nutritional status is not compromised. In the present study, nine patients had a BMI $>25 \text{ kg/m}^2$ and in these, the dietary intervention may have focused on weight maintenance rather than weight gain. The study inclusion criteria did not exclude patients with a BMI $>25 \text{ kg/m}^2$ and, therefore, the results may have been limited regarding improvements in nutritional status. Future studies could select patients with a BMI $<20 \text{ kg/m}^2$ who are more likely to benefit from an improvement in nutritional status by increasing their oral nutritional intake. It could be argued that patients in the current study were not optimally managed before entry into the study and that the improvements observed were not related to the intervention *per se* but as a result of all round care. However, the study patients were medically stable and had been cared for at a national CIF centre for a mean of 81.8 months before entry into the study (Table 1).

Although the instruments used to evaluate quality of life in the present study have been used in patients on HPN, (Richards and Irving, 1997) the need for a validated, treatment-specific tool to measure quality of life in this population has been identified (Baxter *et al.*, 2006). Using the existing quality of life tools, this study found that patients who reduced frequency of infusions, showed an improvement in the EQ-5D index and the SF-36 physical functioning compared to those who maintained infusion frequency. There are limited data on the quality of life of patients with CIF who are not dependent on HPN. In a study of eight HPN and 20 non-HPN dependent patients, Carlsson *et al.*, (2003) found that HPN patients had a worse quality of life score than the non-HPN patients using the SF-36. In the present study, although no differences were found at baseline between those dependent and independent on HPN, after the intervention there were significant changes in several quality of life dimensions with patients dependent on HPN improving more than those who were independent. These findings agree with Rovera *et al* (2000) in which 18 CIF patients were admitted to a specialist treatment facility with the aim of reducing HPN requirements by enhancing nutrient and fluid absorption. Seven patients

were able to become independent of HPN and demonstrated a significant improvement in many of the SF-36 domains. These improvements in quality of life may be related to a reduced frequency of infusions, mediated through less nocturnal disturbance associated with their regimen and a consequent improvement in sleep. Disrupted sleep has been identified as a quality of life issue in HPN patients whilst an increased number of infusions have been associated with a worse quality of life (Pironi *et al.*, 2004). A concern when advising patients with CIF to increase their oral nutrient intake is that this will be accompanied by an increase in gastrointestinal output which is undesirable. However, the use of patient-kept diaries has inherent disadvantages such as excluding those who cannot read or write, dependency on patient motivation and concerns over poor accuracy, missing data and investigator interpretation (Richardson, 1994). Neither of the output diaries has been validated in CIF and using the adapted tools may have diminished their sensitivity and specificity. The practicality of weighing gastrointestinal output was considered but the patients, who were free-living during data collection, were not asked to do so as this was felt to be too burdensome. Future studies might incorporate weighing which would lead to more robust data and the development of suitable validated tools to assess output in this patient group.

Although the intervention in the present study was associated with positive outcomes, its relatively short length and measurements at only two time points means that any sustained improvements or a plateau effect would have not been captured. However, the sustained and positive effects of a structured education programme have been demonstrated over a 12-month period in patients with diabetes (Lemozy-Cadroy *et al.*, 2002). These included a gradual improvement in knowledge which was associated with an improvement in glycaemic control and fewer hospital admissions. The HPN patients studied by Rovera *et al.*, (2000) were followed up for 1 year during which a greater reduction in HPN volume, energy and number of infusion days than in the present study was observed. This suggests that sustainable improvements are possible and worthy of further study.

In conclusion, the provision of an information booklet in conjunction with individually tailored advice significantly improved patient knowledge of the CIF regimen and was associated with a reduction in HPN-dependence. Future randomised controlled trials are required to identify the most effective type of education in CIF including the assessment of the effect of an information booklet with and without individualised advice in order to assess the effectiveness of the booklet in isolation and the influence of the dietitian. The difference between individual and group advice could also be explored in this complex patient population.

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Figures

Figure 1. Trial profile

Figure 2. Factors influencing patient knowledge and subsequent adherence

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Table 1 Demographic and clinical profile of all patients completing the study and subgroup of those on HPN

	All patients (n=48)	HPN (n=33)
Age (years) mean \pm SD	56.1 \pm 13.4	56.2 \pm 14.2
Sex (M:F)	17:31	12:21
Months since referral to CIF centre mean \pm SD (range)	81.8 \pm 86.6 (0 – 367)	65.1 \pm 67.6 (10 – 33)
Aetiology		
Crohn’s disease with multiple bowel resections	25	16
Mesenteric infarction/embolus	12	10
Radiation enteritis	3	2
Surgical resection	5	2
Others ^a	3	3
Length of small bowel (cm)		
\leq 50	16	15
51 – 100	18	11
101 – 200	11	5
>200	3	2
Intestinal anatomy		
Jejunostomy	12	8
Ileostomy	14	7
Colostomy	5	5
No stoma	16	12
Enterocutaneous fistula	1	1

Type of artificial nutrition

Home parenteral nutrition	33	33
Home parenteral fluids	4	0
Subcutaneous fluids	2	0
Oral nutritional supplements	4	0
Intestinal failure diet alone	5	0

^a Pseudo-obstruction, other collagenous colitis and multiple resections due to polyps

Table 2 Change in knowledge, oral intake, intestinal output, nutritional status and quality of life after receiving the intervention in all patients and a subgroup on HPN (Mean \pm SD)

Variable	All patients (n=48)			HPN patients (n=33)		
	Before	After	P value	Before	After	P value
Knowledge %	64.3 \pm 27.6	80.7 \pm 14.8	<0.001	62.3 \pm 28.4	80.9 \pm 13.8	<0.001
Oral intake						
Energy KJ (kcal)	8908 \pm 3745 (2129 \pm 895)	9795 \pm 4113 (2341 \pm 983)	0.04	7142 \pm 2314 (1707 \pm 553)	8343 \pm 3376 (1994 \pm 807)	0.03
Protein (g)	74 \pm 34	77 \pm 32	0.46	61 \pm 27	65 \pm 26	0.40
Fat (g)	93 \pm 42	110 \pm 52	0.003	76 \pm 28	99 \pm 42	0.001
Carbohydrate (g)	250 \pm 116	255 \pm 118	0.72	199 \pm 83	209 \pm 87	0.54
Fibre (g)	9 \pm 5	9 \pm 4	0.48	6.7 \pm 2.6	7.2 \pm 2.9	0.28
Intestinal output score						
Stoma	35 \pm 27	27 \pm 10	0.12	33 \pm 26	26 \pm 12	0.24
In continuity	40 \pm 31	39 \pm 29	0.75	39 \pm 38	38 \pm 33	0.93
Volume (ml)	3503 \pm 2560	3670 \pm 2134	0.55	-	-	-
Nutritional status						
Weight (kg)	62.1 \pm 9.7	62.8 \pm 9.4	0.06	61.3 \pm 9.8	61.7 \pm 9.5	0.43
BMI (kg/m ²)	22.3 \pm 2.9	22.8 \pm 2.6	0.02	21.8 \pm 2.6	22.2 \pm 2.3	0.17
Female - TST (mm)	17.6 \pm 6.9	17.9 \pm 7.1	0.56	15.3 \pm 4.5	15.3 \pm 4.8	0.97
- MAMC (cm)	22.1 \pm 2.6	22.3 \pm 2.6	0.41	21.9 \pm 2.3	22.3 \pm 2.6	0.17
Male - TST (mm)	11.6 \pm 3.9	11.1 \pm 4.3	0.45	12.2 \pm 3.8	11.2 \pm 2.7	0.20
- MAMC (cm)	24.4 \pm 2.2	24.5 \pm 2.2	0.81	24.0 \pm 2.3	24.2 \pm 1.9	0.57
Quality of Life						
EQ-5D VAS	62.8 \pm 22	65.8 \pm 18	0.26	59.3 \pm 21	67.1 \pm 17.1	0.001
Index	0.71 \pm 0.26	0.75 \pm 0.19	0.08	0.67 \pm 0.26	0.77 \pm 0.16	0.007
SF-36 Health Perception	40 \pm 23	43 \pm 25	0.09	42 \pm 23	45 \pm 24	0.06
Physical function	57 \pm 24	57 \pm 23	0.82	54 \pm 23	57 \pm 20	0.34
Role - physical	42 \pm 42	46 \pm 43	0.38	45 \pm 45	51 \pm 42	0.46
Role - emotional	79 \pm 38	77 \pm 40	0.81	75 \pm 41	76 \pm 40	0.89
Social functioning	72 \pm 34	69 \pm 33	0.56	68 \pm 34	68 \pm 34	0.95

Mental health	73 ± 21	73 ± 23	0.77	76 ± 21	72 ± 22	0.53
Body pain	70 ± 24	69 ± 25	0.59	67 ± 70	46 ± 49	0.34
Energy/fatigue	46 ± 24	44 ± 24	0.49	12 ± 1	13 ± 1	0.09
Content of HPN/day						
Energy KJ				4372 ± 1636	3966 ± 1925	0.02
(kcal)				(1045 ± 391)	(948 ± 460)	
Nitrogen (g) ^a				9.4 (8, 11)	9 (8, 11)	0.003
Lipid (KJ)				0 (0, 598)	0 (0, 598)	0.08
(kcal) ^a				0 (0, 143)	0 (0, 143)	
Glucose (KJ)				4084 ± 1498	3757 ± 1791	0.05
(kcal)				976 ± 358	898 ± 428	
Sodium (mmol)				196 ± 137	190 ± 138	0.28
Potassium (mmol)				51 ± 28	50 ± 30	0.34
Frequency of HPN (days/week)				6.3 ± 1.3	5.9 ± 1.5	0.003
Volume (ml/day)				2311 ± 880	2198 ± 950	0.02
^a Median (IQR)						

Table 3. Results of the reliability of measures of gastrointestinal output in patients with a stoma.

Quantity	Mean \pm Standard Deviation (ml)	Coefficient of Variation	Intra-class correlation coefficients
Jejunostomy (n=4)			
Quarter	147 \pm 39	0.27	(*)
Third	221 \pm 60	0.27	0.98
Half	289 \pm 98	0.34	0.84
Two-thirds	349 \pm 112	0.32	(*)
Three-quarters	459 \pm 184	0.40	0.96
Ileostomy (n=4)			
Quarter	178 \pm 46	0.26	0.85
Third	215 \pm 54	0.25	0.92
Half	294 \pm 56	0.19	0.76
Two-thirds	339 \pm 66	0.20	0.94
Three-quarters	433 \pm 63	0.15	0.36

(*) Insufficient data to calculate intra-class correlation

Table 4. Changes in quality of life indices for patient's dependant and independent on HPN (Mean \pm SD)

Variable	No HPN (n=15)	HPN (n=32)	P-value
EQ-5D VAS*	-10 (-25, 10)	5 (1, 15)	0.01
Index*	0.00 (-0.11, 0.04)	0.07 (0.00, 0.13)	0.01
SF-36 Health Perception	1 \pm 12	4 \pm 10	0.47
Physical function	-7 \pm 11	3 \pm 16	0.03
Role – physical	-7.3 \pm 10.9	2.7 \pm 15.6	0.03
Role - emotional*	0 (0, 0)	0 (0, 0)	0.48
Social functioning	-10 \pm 31	0 \pm 36	0.34
Mental health*	-8 (-16, 4)	4 (0, 16)	0.02
Body pain	-10 \pm 17	3 \pm 15	0.02
Energy/fatigue	-13 \pm 17	4 \pm 12	<0.001

*median and inter quartile range