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Behavioural recovery after treatment for varicose veins

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Background: The aim of this study was to assess behavioural recovery from the patient's perspective as a prespecified secondary outcome in a multicentre parallel-group randomized clinical trial comparing ultrasound-guided foam sclerotherapy (UGFS), endovenous laser ablation (EVLA) and surgery for the treatment of primary varicose veins.

Methods: Participants were recruited from 11 UK sites as part of the CLASS trial, a randomized trial of UGFS, EVLA or surgery for varicose veins. Patients were followed up 6 weeks after treatment and asked to complete the Behavioural Recovery After treatment for Varicose Veins (BRAVVO) questionnaire. This is a 15-item instrument that covers eight activity behaviours (tasks or actions an individual is capable of doing in an idealized situation) and seven participation behaviours (what the individual does in an everyday, real-world situation) that were identified to be important from the patient's perspective.

Results: A total of 798 participants were recruited. Both UGFS and EVLA resulted in a significantly quicker recovery compared with surgery for 13 of the 15 behaviours assessed. UGFS was superior to EVLA in terms of return to full-time work (hazard ratio 1.43, 95 per cent c.i. 1.11 to 1.85), looking after children (1.45, 1.04 to 2.02) and walks of short (1.48, 1.19 to 1.84) and longer (1.32, 1.05 to 1.66) duration.

Conclusion: Both UGFS and EVLA resulted in more rapid recovery than surgery, and UGFS was superior to EVLA for one-quarter of the behaviours assessed. The BRAVVO questionnaire has the potential to provide important meaningful information to patients about their early recovery and what they may expect to be able to achieve after treatment.

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Introduction

Minimally invasive treatments for varicose veins such as ultrasound-guided foam sclerotherapy (UGFS) and thermal ablation techniques have become widely used alternatives to surgery for the treatment of varicose veins. One of the advantages of these techniques is the reported quicker return to normal activities, particularly following UGFS^{1–3}. However, it is unclear whether thermal ablation, in particular endovenous laser ablation (EVLA), is also associated with a clinically significant quicker return to normal activities compared with surgery; some studies^{4,5} have shown an earlier return and others^{2,6–8} no difference.

Until recently, there was no standard means of assessing recovery from the patient's perspective. This led to the use of varying definitions such as return to 'normal activities', 'full activity', 'daily activity' or 'basic physical activities' and/or 'return to work' in previous studies. This lack of standardization led the authors to develop a 15-item

questionnaire to assess distinct aspects of normal activities that were identified as important by patients⁹ – the Behavioural Recovery After treatment for Varicose Veins (BRAVVO) questionnaire.

This paper reports behavioural recovery results from a multicentre parallel-group randomized clinical trial (CLASS, Comparison of LAser, Surgery and foam Sclerotherapy) that compared the clinical efficacy and cost-effectiveness of three treatment modalities: UGFS, EVLA with delayed foam sclerotherapy to residual varicosities if required, and surgery. Behavioural recovery was one of the prespecified secondary outcomes of the CLASS trial. The clinical and cost-effectiveness results have been reported elsewhere^{10,11}.

Methods

Patients were recruited from 11 centres in the UK between November 2008 and October 2012. This study

1. Bending the leg(s) (without discomfort):

☐ I don't normally do this

☐ I normally do this, but haven't done so since my treatment

☐ I have done this since my treatment. I did it for the first time:

☐ on the day of my treatment OR ☐ days after my treatment OR ☐ weeks after my treatment

Fig. 1 Question layout

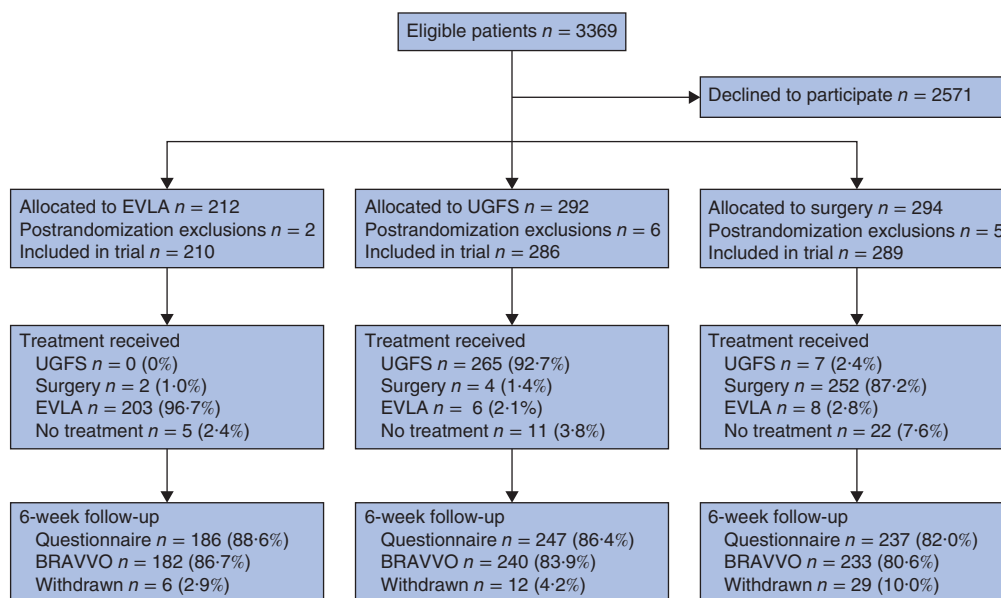


Fig. 2 CONSORT diagram for the trial. Reasons for postrandomization exclusion included: recurrent varicose veins and veins larger than 15 mm. Reasons for withdrawal from follow-up included: patient decided not to proceed with treatment (and also declined follow-up), declined follow-up after treatment or did not wish to complete questionnaires. UGFS, ultrasound-guided foam sclerotherapy; EVLA, endovenous laser ablation

(ISRCTN51995477) had research ethics committee and Medicines and Healthcare products Regulatory Authority approval. Eight centres randomized participants to one of three treatment options, and three centres offered only UGFS and surgery. Participants were randomized between the treatments with even allocation, using a minimization algorithm that included centre, age (less than 50 years, 50 years or more), sex, great saphenous vein (GSV) or small saphenous vein (SSV) reflux, and unilateral or bilateral disease. Inclusion criteria were: age over 18 years; primary unilateral or bilateral symptomatic varicose veins (Clinical Etiologic Anatomic Pathophysiological (CEAP) grade C2 or above); GSV and/or SSV involvement; and reflux exceeding 1 s on duplex ultrasonography. Exclusion criteria

were: current deep vein thrombosis; acute superficial vein thrombosis; a GSV or SSV diameter smaller than 3 mm or larger than 15 mm; tortuous veins considered unsuitable for EVLA or stripping; and contraindications to UGFS or to general/regional anaesthesia that would be required for surgery.

Treatments

The treatments have been described in detail elsewhere^{9,10}. For UGFS, foam was produced using the Tessari technique¹² using a ratio of 0.5 ml sodium tetradecyl sulphate to 1.5 ml air (3 per cent for GSV/SSV truncal veins, 1 per cent for varicosities; maximum 12 ml foam

Table 1 Demographic details at recruitment

	EVLA (<i>n</i> = 210)	UGFS (<i>n</i> = 286)	Surgery (<i>n</i> = 289)
Age (years)*	49.7 (18–80)	49.0 (19–78)	49.2 (22–85)
Sex ratio (F : M)	120 : 90	162 : 124	163 : 126
Body mass index (kg/m ²)*	27.0 (17–42)	27.1 (17–44)	27.7 (17–44)
Unilateral disease	153 (72.9)	215 (75.2)	196 (67.8)
Employment status			
Self-employed	21 (10.2)	37 (13.0)	29 (10.3)
Employed	120 (58.3)	169 (59.3)	179 (63.5)
Other	65 (31.6)	79 (27.7)	74 (26.2)
Unknown	4	1	7
Saphenous vein involvement			
Great saphenous	182 (86.7)	232 (81.1)	239 (82.7)
Small saphenous	14 (6.7)	21 (7.3)	21 (7.3)
Great and small saphenous	14 (6.7)	33 (11.5)	29 (10.0)
Deep vein reflux	28 of 205 (13.7)	47 of 280 (16.8)	25 of 282 (8.9)
CEAP classification			
C2, varicose veins over 3 mm	113 (54.1)	169 (59.1)	147 (51.2)
C3, oedema	28 (13.4)	35 (12.2)	39 (13.6)
C4, skin/subcutaneous changes	56 (26.8)	74 (25.9)	90 (31.4)
C5/C6, healed/active venous ulcer	12 (5.7)	8 (2.8)	11 (3.8)
Unknown	1	0	2

Values in parentheses are percentages unless indicated otherwise; *values are mean (range). EVLA, endovenous laser ablation; UGFS, ultrasound-guided foam sclerotherapy; CEAP, Clinical Etiologic Anatomic Pathophysiologic.

per session). EVLA of GSVs/SSVs was performed under local anaesthetic, and patients were offered UGFS to any residual varicosities at 6-week follow-up if required, with the exception of one centre that performed concurrent phlebectomies. Surgery in the form of proximal GSV/SSV ligation and stripping (all GSV) and concurrent phlebectomies was performed under general or regional anaesthetic as a day-case procedure. Compression stockings were applied after all three treatments.

Post-treatment activity

All participants were given a study patient information leaflet (PIL), which recommended a return to all normal activities as soon as they were able, but that strenuous activity/contact sport should be avoided for 1–2 weeks. The PIL specifically stated that following EVLA or UGFS ‘most people are able to return to work within 2–3 days of treatment, but some people go back the following day or even the same day’, and that following surgery ‘people can return to office or sedentary work after 2–3 days; and that most people will be back at work within a week after surgery to one leg and 2 weeks after surgery to both legs; but there is no reason to remain off work as long if it can be managed with reasonable comfort’. Participants undergoing UGFS or EVLA were advised to wear compression stocking for 10 days constantly (day and night). Those in the surgery group were advised that bandages would be removed the day after operation, following which they

should wear a stocking for 10 days, but that it was reasonable to remove the stocking after 4 or 5 days, providing that they were active.

Data collection

The participants were asked to complete the BRAVVO questionnaire along with other study questionnaires (Aberdeen Varicose Vein Questionnaire, EQ-5D™ (Euro-QoL, Rotterdam, The Netherlands) and Short Form 36 (QualityMetric, Lincoln, Rhode Island, USA)) at the 6-week follow-up appointment. Participants who failed to attend the 6-week appointment were sent the questionnaire to complete at home.

The BRAVVO questionnaire was developed as an instrument to assess the activity and participation components of the World Health Organization International Classification of Disability and Function model¹³. Variation in activity and participation is not fully explained by impairment and so these constructs are important additional indicators of health outcome. An interview study involving 17 patients who had recently undergone varicose vein treatment was carried out to identify normal activities and ‘milestone’ behaviours to incorporate into the questionnaire. In addition to sampling from the three treatment options, diversity sampling was used in an attempt to gain a mix of sex, age and rural–urban location. Seventeen interview transcripts were content-analysed in four stages

Table 2 Behavioural recovery: ultrasound-guided foam sclerotherapy *versus* surgery

	Proportion carrying out behaviour (%)	Time until specified proportion of participants could carry out behaviour (days)*		
		UGFS	Surgery	Hazard ratio†
Activity items				
Bending the legs without discomfort	50	3.0	4.6	1.38 (1.14, 1.67)
	90	14.1	21.3	
Lifting heavy objects without discomfort	50	4.8	9.8	1.97 (1.59, 2.44)
	90	16.9	34.5	
Moving from standing to sitting without discomfort	50	1.9	3.7	1.63 (1.35, 1.97)
	90	9.3	17.5	
Standing still for a long time (> 15 min) without discomfort	50	3.9	7.1	1.67 (1.36, 2.05)
	90	15.8	28.7	
Walking short distances (< 20 min) without discomfort	50	1.9	4.4	2.00 (1.65, 2.42)
	90	8.2	19.1	
Walking long distances (> 20 min)	50	4.5	8.0	1.76 (1.45, 2.14)
	90	15.2	27.1	
Having a bath or shower	50	5.4	4.9	0.85 (0.70, 1.03)
	90	11.4	10.3	
Driving a car	50	4.1	7.0	1.78 (1.45, 2.19)
	90	12.4	21.1	
Participation items				
Doing housework	50	2.1	4.5	2.10 (1.72, 2.56)
	90	7.3	15.7	
Looking after children	50	1.2	3.5	2.20 (1.61, 3.00)
	90	6.2	17.9	
Wearing clothes that show the legs	50	12.4	12.8	1.03 (0.78, 1.35)
	90	56.6	58.7	
Partial return to normal work/employment	50	4.4	9.9	2.16 (1.72, 2.72)
	90	15.4	34.2	
Full return to normal work/employment	50	4.8	11.7	2.56 (2.05, 3.21)
	90	14.9	36.2	
Going out socially	50	7.1	9.3	1.29 (1.06, 1.57)
	90	25.8	34.0	
Sporting activity or exercise	50	15.7	21.8	1.33 (1.05, 1.68)
	90	62.6	86.7	

Values in parentheses are 95 per cent c.i. *The 50 per cent value is equivalent to the median time to return to the behaviour. †A hazard ratio greater than 1.00 shows that return to the behaviour took longer in the surgery arm. UGFS, ultrasound-guided foam sclerotherapy.

to identify appropriate items to include in a questionnaire. Full details of this process have been published previously⁹.

The BRAVVO questionnaire assesses the time taken for patients to return to performing 15 behaviours: eight 'activity' behaviours (tasks or actions an individual is capable of doing in an idealized situation) and seven 'participation' behaviours (what the individual does in an everyday, real-world situation) that were identified to be important from the patient's perspective⁹. Fig. 1 shows the question layout.

Statistical analysis

Data from the BRAVVO questionnaire were analysed within an interval-censored time-to-event framework using flexible parametric survival models¹⁴. For each behaviour item, each participant's response was converted

into the number of days to return to that behaviour. If a participant indicated that return to the behaviour was on the day of the procedure, this was assumed to be interval-censored between day 0 and day 1. If a participant indicated return to the behaviour was after a number of weeks, not days, this was assumed to be interval-censored between the previous week and the week indicated. For example, if a participant reported 5 weeks, it was assumed that the return to the behaviour took place between 28 and 35 days. A participant who indicated that they had not returned to a behaviour that they usually performed was right-censored at 42 days. Participants who indicated that they did not normally perform a specific behaviour were not included in analysis of that behaviour. No missing data were imputed.

Data are reported as the number of days for 50 and 90 per cent of participants to return to each behaviour,

Table 3 Behavioural recovery: endovenous laser ablation *versus* surgery

	Proportion carrying out behaviour (%)	Time until specified proportion of participants could carry out behaviour (days)*		Hazard ratio†
		EVLA	Surgery	
Activity items				
Bending the legs without discomfort	50	2.7	4.6	1.49 (1.19, 1.75)
	90	12.6	21.3	
Lifting heavy objects without discomfort	50	5.9	9.8	1.79 (1.39, 2.27)
	90	20.5	34.5	
Moving from standing to sitting without discomfort	50	2.2	3.7	1.56 (1.27, 1.96)
	90	10.4	17.5	
Standing still for a long time (> 15 min) without discomfort	50	4.8	7.1	1.41 (1.11, 1.79)
	90	20.0	28.7	
Walking short distances (< 20 min) without discomfort	50	3.0	4.4	1.30 (1.04, 1.61)
	90	13.2	19.1	
Walking long distances (> 20 min)	50	5.6	8.0	1.53 (1.06, 1.67)
	90	19.8	27.1	
Having a bath or shower	50	5.5	4.9	0.74 (0.59, 0.93)
	90	12.8	10.3	
Driving a car	50	4.4	7.0	1.82 (1.43, 2.33)
	90	12.7	21.1	
Participation items				
Doing housework	50	2.5	4.5	1.89 (1.49, 2.38)
	90	8.4	15.7	
Looking after children	50	1.9	3.5	1.61 (1.15, 2.27)
	90	8.8	17.9	
Wearing clothes that show the legs	50	14.6	12.8	0.97 (0.69, 1.35)
	90	75.1	58.7	
Partial return to normal work/employment	50	6.3	9.9	1.75 (1.33, 2.27)
	90	21.1	34.2	
Full return to normal work/employment	50	7.7	11.7	1.79 (1.37, 2.27)
	90	23.5	36.2	
Going out socially	50	6.9	9.3	1.41 (1.12, 1.75)
	90	23.9	34.0	
Sporting activity or exercise	50	14.2	21.8	1.47 (1.12, 1.92)
	90	55.5	86.7	

Values in parentheses are 95 per cent c.i. *The 50 per cent value is equivalent to the median time to return to the behaviour. †A hazard ratio greater than 1.00 shows that return to the behaviour took longer in the surgery arm. EVLA, endovenous laser ablation.

estimated from the parametric survival models (the 50 per cent value represents the median time to return to this behaviour). Extrapolation beyond the 42-day cut-off was performed for behaviours where 90 per cent of participants had not returned to the behaviour by 42 days. Treatment effects are presented as hazard ratios with associated 95 per cent c.i. All analyses were carried out in Stata® 12¹⁵. Flexible parametric survival models were fitted using the *stpm* package¹⁶.

Results

Seven hundred and ninety-eight participants were recruited, of whom 13 were ineligible (for example because they had recurrent veins or veins larger than 15 mm in diameter) after randomization and were considered postrandomization exclusions (*Fig. 2*). The groups were well balanced in terms of demographic characteristics

at baseline, but there was an increased incidence of deep venous reflux in the foam group compared with the surgery group ($P = 0.005$) (*Table 1*). Of the 670 participants who completed the 6-week questionnaire, 655 completed at least one of the BRAVVO questions. Completion rates were slightly lower for the questions about going out socially (74.8 per cent) and sporting activity (66.0 per cent), which may not have been relevant to all participants. For all behaviours, except wearing clothes that show the leg, going out socially and sporting activities, over 95 per cent of participants had returned to normal behaviour within 6 weeks of intervention.

Ultrasound-guided foam sclerotherapy *versus* surgery

Participants randomized to UGFS recalled being able to carry out 13 of the 15 behaviours significantly more

Table 4 Behavioural recovery: endovenous laser ablation *versus* ultrasound-guided foam sclerotherapy

	Proportion carrying out behaviour (%)	Time until specified proportion of participants can carry out behaviour (days)*		Hazard ratio†
		EVLA	UGFS	
Activity items				
Bending the legs without discomfort	50	2.7	3.0	0.94 (0.75, 1.17)
	90	12.6	14.1	
Lifting heavy objects without discomfort	50	5.9	4.8	1.11 (0.87, 1.42)
	90	20.5	16.9	
Moving from standing to sitting without discomfort	50	2.2	1.9	1.12 (0.90, 1.40)
	90	10.4	9.3	
Standing still for a long time (> 15 min) without discomfort	50	4.8	3.9	1.14 (0.90, 1.44)
	90	20.0	15.8	
Walking short distances (< 20 min) without discomfort	50	3.0	1.9	1.48 (1.19, 1.84)
	90	13.2	8.2	
Walking long distances (> 20 min)	50	5.6	4.5	1.32 (1.05, 1.66)
	90	19.8	15.2	
Having a bath or shower	50	5.5	5.4	1.19 (0.96, 1.48)
	90	12.8	11.4	
Driving a car	50	4.4	4.1	0.95 (0.74, 1.21)
	90	12.7	12.4	
Participation items				
Doing housework	50	2.5	2.1	1.03 (0.82, 1.29)
	90	8.4	7.3	
Looking after children	50	1.9	1.2	1.45 (1.04, 2.02)
	90	8.8	6.2	
Wearing clothes that show the legs	50	14.6	12.4	1.17 (0.83, 1.64)
	90	75.1	56.6	
Partial return to normal work/employment	50	6.3	4.4	1.17 (0.89, 1.52)
	90	21.1	15.4	
Full return to normal work/employment	50	7.7	4.8	1.43 (1.11, 1.85)
	90	23.5	14.9	
Going out socially	50	6.9	7.1	0.88 (0.70, 1.10)
	90	23.9	25.8	
Sporting activity or exercise	50	14.2	15.7	0.80 (0.61, 1.04)
	90	55.5	62.6	

Values in parentheses are 95 per cent c.i. *The 50 per cent value is equivalent to the median time to return to the behaviour. †A hazard ratio greater than 1.00 shows that return to the behaviour took longer in the endovenous laser ablation (EVLA) arm. UGFS, ultrasound-guided foam sclerotherapy.

quickly than those randomized to surgery (Table 2). The two behaviours for which there was no evidence of a difference in the time to recover between the trial arms were 'having a bath or shower' and 'wearing clothes that show the legs'. In general, the median time to return to the activity behaviours was 5 days or less for those randomized to UGFS and up to 9 days for those randomized to surgery. In both groups, there was greater variation in the median time to return to the participation behaviours than the activity behaviours.

Endovenous laser ablation *versus* surgery

Participants randomized to EVLA recalled being able to carry out 13 of the 15 behaviours significantly more quickly than those randomized to surgery (Table 3). Return to 'having a bath or shower' was quicker after surgery than after

EVLA. There was no difference in time to return to the participation behaviour of 'wearing clothes that show the legs'.

Endovenous laser ablation *versus* ultrasound-guided foam sclerotherapy

There were no differences in the time taken to return to 11 of the 15 behaviours between participants randomized to EVLA and those randomized to UGFS (Table 4). Return to 'walking short distances without discomfort', 'walking long distances', 'looking after children' and 'full return to normal work/employment' took longer for the EVLA group than the UGFS group. Following UGFS or EVLA only one-third of the specific behaviours could be carried out by 50 per cent of participants by 3 days after treatment.

Discussion

This study showed that both UGFS and EVLA resulted in a more rapid recovery compared with surgery for 13 of the 15 behaviours. UGFS was superior to EVLA in terms of return to full time work, looking after children and walking (both short and long distances). Importantly, the specific behaviours assessed were shown to have a range of different recovery trajectories.

Previous randomized clinical trials showed behavioural recovery to be more rapid following UGFS compared with surgery^{1,2}, but the benefit of EVLA over surgery was less clear^{2,4,8}. In this study, for all but two behaviours (wearing clothes that showed the legs and showering/bathing) the recovery was quicker following UGFS or EVLA compared with surgery. These findings may have arisen as a result of information contained in the study PIL, which recommended that compression hosiery was worn continuously for 10 days following UGFS or EVLA but for 4–5 days routinely after surgery.

In the comparison between UGFS and EVLA, behavioural recovery was faster following UGFS for four of the 15 behaviours; there was no difference between the groups for the other behaviours. Two previous randomized trials^{2,3} showed earlier return to 'normal activities' in patients undergoing UGFS compared with EVLA. Specifically, the present study showed a quicker return to full-time work following UGFS, similar to the findings of Rasmussen and colleagues². The median time taken to return to work following EVLA (7.7 days) was within the ranges reported^{2,4–8}. However, Rasmussen and colleagues² reported earlier return to work after UGFS compared with the present study (median 2.9 *versus* 4.8 days respectively). A partial explanation of the difference between the two studies may be that, unlike the previous study, the present analysis did not correct for weekends.

For other behaviours, the recalled recovery times following both UGFS and EVLA were longer than might be expected from the literature^{2–5,8}. This may be explained by the timing of the questionnaire at 6 weeks, and thus it is the nature of the differences between treatment groups rather than the absolute timings taken to return to these activities that the authors wish to highlight in this paper.

The extent of this overall delay in recovery is hard to justify, particularly in light of the standard information and advice given in the study PIL. There may have been a number of external influences affecting participants' recollection of their recovery, including misinformation and fear. Although attitudes to recovery and return to normal behaviours have changed in secondary care, this may not have filtered into primary care or 'public knowledge'.

Fear of activity or fear of pain caused by activity has been documented following surgery for other conditions^{17,18}. It is possible that some people undergoing treatment for varicose veins experience similar fears, and this may limit or restrict their activity following treatment. With regard to return to work, there are clearly a number of additional factors that might play a role, such as a person's employment status (employed or self-employed), the sickness benefits they are entitled to, the type of work they are employed to do, how long they are 'signed off' by the doctor, and the views of their employer on return to work after an operation. It should be noted that this study distinguished between partial and full return to work, and that no difference was noted in partial return to work following UGFS and EVLA. This finding may be of substantial importance to patients, their employers and the economy as a whole.

The main strength of this study is that the behaviours investigated were based on systematic investigation of the recovery milestones that are important to patients following treatment for varicose veins. Hence, the findings are of personal importance from a patient perspective. Distinguishing between the behaviours that contribute to 'normal activity' helps build a profile of recovery that may be particularly useful for patients preparing for, or recovering from, treatment. Furthermore, the methodology used to develop the BRAVVO questionnaire could be used in other conditions to provide normative information about behavioural recovery that is relevant to patients. The BRAVVO questionnaire was pilot tested and found to be acceptable to patients, comprehensible and appropriate for self-completion. Despite this, a potential weakness of the study is that the level of missing data in the BRAVVO questionnaire was higher for two of the questions. Further work to reformat or rephrase the questions or response options may help minimize levels of missing data. A further potential weakness is the choice of assessment time point (6 weeks after treatment). This may have compromised recall, particularly for behaviours that participants were able to return to a short time after treatment; however, any compromise in recall is likely to have affected the three treatment groups equally. Other study outcomes were assessed at 6 weeks, and behavioural recovery was assessed at the same time point to minimize participant burden. Further work is required to determine the optimal timing(s) of this questionnaire. Given that the median time to return to the behaviour was less than 14 days for 13 of the behaviours, and up to 22 days for the other two (wearing clothes that show the legs, sporting activity or exercise), the use of the questionnaire at approximately 2–3 weeks would seem appropriate.

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