

## Title page

Title: Is Sense of Coherence a predictor of lifestyle changes in subjects at risk for type 2 diabetes?

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## **ABSTRACT**

*Objective:* To determine whether the sense of coherence (SOC) could predict the outcome of an 18-month lifestyle intervention program for subjects at risk of type 2 diabetes.

*Methods:* Subjects at high risk of type 2 diabetes mellitus were recruited to a low-intensity lifestyle intervention program by their general practitioners. Weight reduction  $\geq 5\%$  and improvement in exercise capacity of  $\geq 10\%$  from baseline to follow-up indicated a clinically significant lifestyle change. SOC was measured using the 13-item SOC questionnaire.

*Results:* The study involved 213 subjects with a mean body mass index of 37 (SD  $\pm$  6). Complete follow-up data were obtained for 131 (62%). Twenty-six participants had clinically significant lifestyle changes. There was a 21% increase in the odds of a clinically significant lifestyle change for each point increase in the baseline SOC score (odds ratio = 1.21; confidence interval = 1.11–1.32). The success rate was 14 times higher in the highest SOC score tertile group compared with the lowest.

*Conclusion:* High SOC scores were good predictors of successful lifestyle change in subjects at risk of type 2 diabetes. SOC-13 can be used in daily practice to increase clinical awareness on the impact of mastery on the outcome of life-style intervention programs.

**Keywords:** lifestyle, obesity, prevention, quality of life, sense of coherence, type 2 diabetes mellitus

## **Trial registration**

ClinicalTrials.gov: NCT00202748

## **Introduction**

The prevalence of type 2 diabetes is increasing worldwide. Changes in lifestyle factors such as diet and physical activity are suggested to be the main reasons for this increase (1). The effective reduction of type 2 diabetes is possible if subjects at high risk make lifestyle modifications (2;3), although sustained lifestyle change such as that needed to avoid type 2 diabetes may be difficult to achieve (4). Thus, it is a challenge for subjects at risk to achieve desirable, permanent lifestyle changes. Moreover, it is difficult for clinicians to identify the subjects who are most likely to profit from a lifestyle modification program, thereby improving cost-effectiveness. Many studies have found that a positive health outcome can be predicted using the Sense of Coherence (SOC) questionnaire (5-8). The present study examined whether this simple assessment of the personality trait of mastery can be used as a tool to estimate the likelihood that subjects will achieve successful lifestyle changes.

The salutogenic theory, which focuses on predictors of positive health outcomes, was introduced in the 1970s by Antonovsky, who was interested in stress theory. Based on a study of healthy survivors from concentration camps in the Second World War, he postulated three important properties that allowed them to remain healthy despite their experiences: a) the ability to understand what happens, b) the ability to manage the situation alone or through significant others and c) the ability to find meaning in the situation. According to this theory, the ability to use your own resources is more important than the resources themselves (9;10). This ability is referred to as the SOC, which can be defined as a way of viewing life or mastery (9;10). The concept of SOC was shown to have the capacity to predict future health outcomes (9). Thus, the aim of the present study was to determine whether SOC at baseline could predict the outcomes of a low-intensity lifestyle intervention programme for subjects at risk of type 2 diabetes, and to assess the predictability of other simple demographic factors.

## **Methods**

## Subjects and study design

The study sample comprised subjects at high risk of type 2 diabetes mellitus who were referred to the local hospital by their general practitioner (GP). The “Finnish Diabetes Risk score” was used by GPs to select subjects based on traditional risk factors for type 2 diabetes, such as the body mass index (BMI), waist circumference, inactivity and age (11). The study operated from March 2004 to September 2005 and there was an 18-month follow-up period. This study was part of a randomized controlled trial, where one group received personal advice and another group received personal advice plus group sessions. There were no important outcome differences between these two treatment groups, as described previously (12), so the results were combined for all participants for the purpose of this study. Written informed consent was obtained. The details of the recruitment methods, the intervention program and the main results have been published previously (12). The study was approved by the Regional Committee for Medical Research Ethics of Southern Norway.

## Assessments

Body weight and the results of a physical test on a treadmill, using a modified Bruce protocol for subjects in poor physical condition (13), were determined at baseline and at follow-up. Based on normative data for the maximal aerobic capacity ( $\text{VO}_2 \text{ max}$ ) with respect to gender and age, the subjects were classified into six levels, i.e., very poor, poor, fair, good, excellent and superior aerobic capacity (14). A clinically significant lifestyle change was characterized as a weight reduction of  $\geq 5\%$  and an improvement in the  $\text{VO}_2 \text{ max}$  of  $\geq 10\%$  from baseline to follow-up (12). The health-related quality of life (HRQOL) was assessed at baseline and follow-up using the Medical Outcomes Survey Short Form 36 (SF-36), and the results were used to calculate a physical component summary (PCS) and a mental component summary (MCS). The SF-36 is used internationally as a generic measure of self-reported HRQOL (15).

The scores for PCS and MCS range from 0 (worst possible) to 100 (best possible health state), where the results are standardized to fit a mean score of 50 to the general population (15;16). Changes in the PCS and MCS scores of 2–5 points are defined as small clinically significant changes, whereas changes of 5–8 and  $\geq 8$  are defined as moderate and large clinically important changes, respectively (17). The instrument used to measure mastery at an individual level was the SOC questionnaire. The two most widely used versions of the SOC questionnaire are the original version with 29 items and a shorter version with 13 items (9). The correlation between SOC-29 and SOC-13 is good ( $r = 0.96$ ) (18), so we used the short version in the present study. According to Antonovsky's three postulated properties, the questionnaire examines three sub-dimensions: meaningfulness, comprehensibility and manageability (9;19). SOC-13 was shown to be reliable, valid, feasible and cross-culturally applicable (9). Subjects were asked to indicate their level of agreement with each of the items on a seven-point scale (1 = never, 7 = always). The total score was summed, which could range from 13 (low SOC) to 91 (high SOC), where a higher score indicated a stronger SOC or mastery. Many studies have shown that the SOC changes with time, but Antonovsky assumed that it would stabilize in early adulthood with marginal subsequent fluctuations (9;20-22). The aim of the present study was to explore baseline predictors, so SOC was only measured at baseline.

### Definition of end points

The primary outcome of this study was to evaluate the objective predictors for a successful, clinically significant lifestyle change, which were defined as weight reduction  $\geq 5\%$  and an improvement in the exercise capacity of  $\geq 10\%$  from baseline to follow-up (12).

### Statistical analyses

The statistical analyses were performed with the Statistical Package for Social Sciences version 18.0 (SPSS) using descriptive analyses of the baseline characteristics. Clinically significant lifestyle changes, the SF-36 PCS and MCS scores and their changes were computed, as well as the baseline SOC scores. To produce a prognostic model of successful lifestyle change, a multivariable logistic regression analysis was conducted using the combined objective clinically important lifestyle change as the dependent variable with the various demographic and clinical variables, the SF-36 scores and the SOC scores as explanatory variables. To use SOC as an explanatory variable, we analyzed the results for each single question separately, each of the three scores for the sub-dimensions (meaningfulness, comprehensibility and manageability) and the total SOC score. Different methods were tested (enter, forward and backward) and the final adjusted model was obtained using the “enter” method of logistic regression analysis by including all of the independent variables in the model, regardless of the level of significance obtained for each separate variable. Unadjusted multivariate logistic regression analyses were also performed for comparison, where the odds ratios (ORs) were used to describe the bivariate associations. Based on the multivariate logistic regression analysis, a receiver operating characteristic (ROC) curve was constructed and the area under the curve (AUC) was used to assess the sensitivity and specificity of the combined predictors. Theoretically, the AUC ranges from 0 to 1, with 1 as a perfect test, implying 100% sensitivity and specificity, and 0.5 as the worst possible value (no better than a random guess) (23;24). Furthermore, based on the absolute rates of successful lifestyle change, we calculated the numbers needed to treat (NNT) to achieve one successful lifestyle change ( $1/\text{absolute ratio of success}$ ), which has the advantage that it yields both the statistical significance and the clinical effort needed to achieve an important clinical outcome. These calculations were also performed based on the intention to treat (ITT) principle, assuming that all drop-outs and those with incomplete data did not

achieve the combined life style change. This avoids any bias caused by omitting these participants from the main analyses. All of the confidence intervals (CI) were set at 95% and the level of significance was set at  $\alpha \leq 0.05$ .

## **Results**

We randomly allocated 213 subjects to the study, of whom 182 (85%) completed the study and 131 (62%) provided complete data in terms of their change in weight and aerobic capacity ( $\text{VO}_2 \text{ max}$ ). The mean BMI was 37 ( $\text{SD} \pm 6$ ), 90% of participants were obese ( $\text{BMI} > 30$ ) and more than half of the participants had a poor aerobic capacity at baseline (Table 1). The SOC score ranged from 27 to 89 with a mean score of 63 ( $\text{SD} \pm 14$ ). There were no significant differences in the SOC score with respect to gender, home relations or educational categories, but the scores were significantly lower for daily smokers (60 ( $\text{SD} \pm 14$ )), subjects who were not working (58 ( $\text{SD} \pm 15$ )) and the subjects who dropped out of the study (49 ( $\text{SD} \pm 8$ )) compared with their counterparts. Objective combined lifestyle changes, i.e., a clinically significant weight reduction and an improved exercise capacity, were achieved by 26 subjects.

According to the multivariate logistic regression analyses, very similar clinical and statistical results were given by the different methods, i.e., enter, forward and backward. Using the enter method of logistic regression analysis, i.e., including all of the independent variables in the model the best predictor of success was a high total SOC score. In this model the total SOC score was clearly associated with the combined lifestyle change, with an adjusted OR for a clinically significant lifestyle change of 1.21 ( $\text{CI} = 1.11\text{--}1.32$ ) for each additional SOC point (Table 2). This correlation differed little in the unadjusted model (1.17 (1.09–1.24)). A ten point higher SOC score was correlated with an OR for successful lifestyle change of 6.7 (2.8–16.1). Neither any single question nor any of the three sub-dimensions (meaningfulness, comprehensibility and manageability) in the SOC questionnaire was associated with

successful lifestyle change. There was also a statistically significant association between a successful lifestyle change and a decreased physical HRQOL (lower PCS) according to SF-36 (Table 2), which yielded an adjusted OR of 1.08 (1.00–1.16) for each point decrease in the PCS score.

After dividing the subjects in this study into tertiles according to their SOC scores, the lowest tertile had a mean (SD) SOC score of 47.8 (7.5), the medium tertile had a score of 64.7 (4.0) and the highest tertile had a score of 78.0 (4.9). The proportions who dropped out from the final aerobic test and provided incomplete data were 53%, 23% and 26% in the low, medium and high SOC tertile groups, respectively. Among the 26 subjects who achieved success, one was in the lowest SOC tertile, four in the medium tertile and 21 in the highest tertile. Thus, among the participants with complete data, the proportions who succeeded were 3%, 8% and 44% in the low, medium and high SOC tertile groups, respectively (Fig. 1). The corresponding results when the intention to treat principle was used were 2%, 6% and 32%, respectively (Fig. 1, Table 3). No participants with a SOC score < 45 achieved a clinically significant lifestyle change. Thus, the NNT to achieve one successful lifestyle change among those who completed the trial as planned differed greatly according to the SOC tertiles, i.e., the NNTs were 31, 13, and 2 in the low, medium and high SOC tertile groups, respectively (Fig. 2). With the ITT principle applied, the NNT figures were of course higher, and especially for the low tertile group.

## **Discussion**

The present study showed that a high level of mastery, which was assessed using the SOC questionnaire, was associated with an increased likelihood of successful lifestyle change for subjects at risk of type 2 diabetes, and vice versa.

The limitations of this study must also be considered. The results may have been weakened by the dropout rate of 15% and complete follow-up data were only obtained from 62% of the participants. This problem is highlighted further by the fact that the baseline characteristics of the completers and dropouts differed significantly (12), thereby suggesting a possibility of attrition bias (25). However, many studies of exercise testing obtained follow-up data from less than two-thirds of the randomized participants (26-28), and the statistically significant correlations connected to the SOC scores, i.e., the main message of this paper, were especially robust ( $p < 0.001$ ).

In this study, we tested the possibility of using the SOC score to predict a successful lifestyle change, i.e., its predictive validity. We found that the predictive validity was acceptable and the frequency of drop-out in the low SOC tertile, was double that in the medium and high SOC tertiles. Divergent results have been reported previously, but a number of studies have found that a high SOC score can predict positive health outcomes, e.g., among survivors of a ferry disaster, patients with chronic lower back pain, patients receiving surgery for morbid obesity and unemployed subjects with somatic disorders undergoing vocational rehabilitation (5-8). However, a systematic review concluded that the SOC questionnaire should not be recommended as a screening instrument due to inadequate definition of appropriate cut-off levels, i.e. it is not clear where SOC no longer protects the movement towards the healthy end (9). There is also a risk of negative health effects if one stigmatizes people in groups regarding their SOC. Instead, it has been suggested that the SOC concept could be implemented as a systematic orientation and perspective in the daily activities of the professionals (9). SOC seems a suitable tool for increasing the professionals' awareness of the individual mastery levels. This awareness will promote the professionals' and researchers' ability to develop and assess sensible future intervention programs for those with low mastery. When the NNT was 2–3 in the present study for subjects in the high SOC tertile, a

cost-effective intervention is certainly indicated. When the NNT was 31 for subjects in the low SOC tertile, another approach with a better likelihood of success would be more appropriate. However, such programs adapted for patients with low mastery has not been developed yet. But an increased clinical awareness of patients with low mastery through SOC evaluation may increase the likelihood that such programs can be developed. Thus, our suggestion is that SOC could be used for screening to increase clinical awareness on those with low mastery, but until further research has answered our questions, not for the selection to current intervention programs.

In general, predictors of weight loss and weight maintenance have been reported to be weak in previous studies. These predictors are often heterogeneous and most regression models explain no more than 25–30% of the variance in weight loss (29). Factors such as self-esteem, motivation, dietary behaviors and exercise may be important correlates of success, but the magnitude of the variance they explain appears to be small and it can be highly variable between different groups (29). The use of SOC may, when future research has answered important questions, make it easier to exclude subjects who will not benefit from a specific lifestyle change program, thereby improving cost-effectiveness and guiding the subjects towards more suitable interventions. Our ROC curve analysis assessed the accuracy of the model's ability to separate positive cases from negative cases, and the AUC of 0.87 (0.80–0.95) was acceptable (Fig. 3). The AUC of 0.84 (0.75–0.93) for SOC in the univariate model implies a 84% higher probability of successful lifestyle change for a participant with a high SOC score versus a participant with a low SOC score. This type of knowledge may appear clinically important for the allocation of future health care resources.

The present study showed that low mastery, which was assessed based on the SOC score, was associated with a lower ability to achieve desirable lifestyle changes in subjects at risk of type 2 diabetes. A low SOC score has also been associated with an increased risk of myocardial

infarction, type 2 diabetes, lower physical activity, unhealthy food choices and all-cause mortality (30-35). Kouvonen et al. found that both unhealthy lifestyle choices and a stress-inducing tendency/inadequate coping system could explain the association between low SOC and type 2 diabetes (30). Thus, low mastery *per se* may be considered a major health problem that is associated with an unhealthy lifestyle, difficulty making lifestyle changes, and, ultimately, it is linked directly with morbidity and mortality.

An interesting and widely discussed topic related to SOC, is its stability. According to Antonovsky, SOC stabilizes in early adulthood with marginal subsequent fluctuations (9). However, even Antonovsky believed that the SOC may be mutable, so it may be considered more as a “dispositional orientation” than a personality trait (9). It is now well documented that SOC tends to increase with age and it can be changed markedly by dramatic life events (weakened by negative life experiences and strengthened by positive experiences) or via therapeutic interventions (9;36-38). This provides hope for subjects with low SOC scores because positive life experiences, interventions and age appear to increase the SOC score. In our study, however, the mean SOC score was not higher for subjects aged  $\geq 46$  years compared with those below this age.

In addition to the SOC score, a decreased physical HRQOL (low PCS) was correlated with an increased likelihood of desirable lifestyle changes. Subjects with a lower PCS score may feel more uncomfortable and more physically impaired, and both conditions may motivate them to make lifestyle changes.

“Lifestyle diseases” are now a well-known concept and a huge number of conditions should be treated at least partly with lifestyle changes. In the present study, 90% of the subjects were obese and many had tried numerous different therapies with disappointing results. Thus, it is crucial not to guide them towards a new disappointment, which would be detrimental for their

self-image and their self-confidence. This may also be demotivating for health professionals. Treating a high number of patients where only a few achieve the desired results is not a cost-effective allocation of scarce resources. Thus, a baseline assessment with SOC is recommended, mainly to improve awareness of the participants with a very low likelihood of a positive health outcome, for whom more appropriate, motivational approaches may be developed. These suggestions should be tested in future research.

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### **Ethical approval**

Ethical approval was obtained from the Regional Committee for Medical Ethics of Southern Norway.

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### **Competing interest**

The authors declare that they have no competing interests.

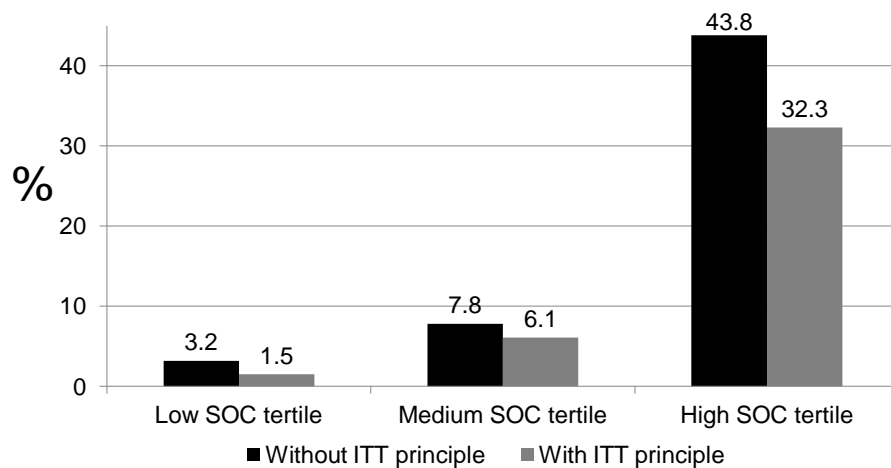
**Authors' contributions** VN and FG participated in the design and coordination of the study. VN performed a literature review, did all the clinical work and was the main author of the manuscript. FG and GR helped draft the manuscript and provided advice on data analyses. All authors read and approved the final manuscript.

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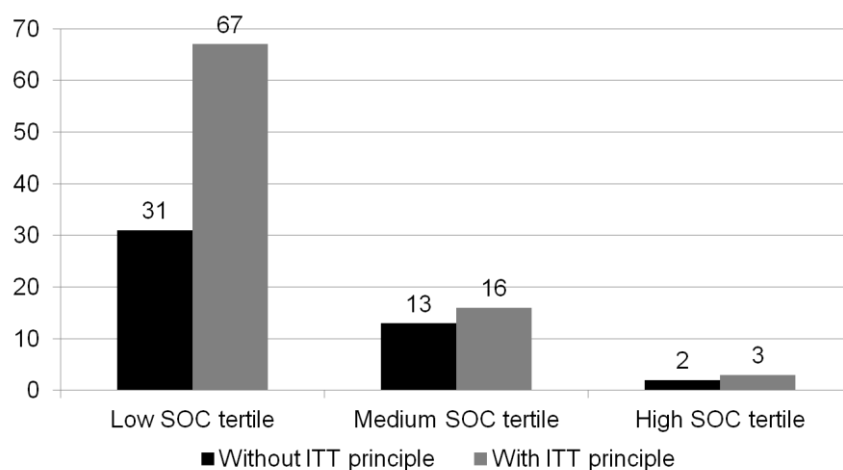
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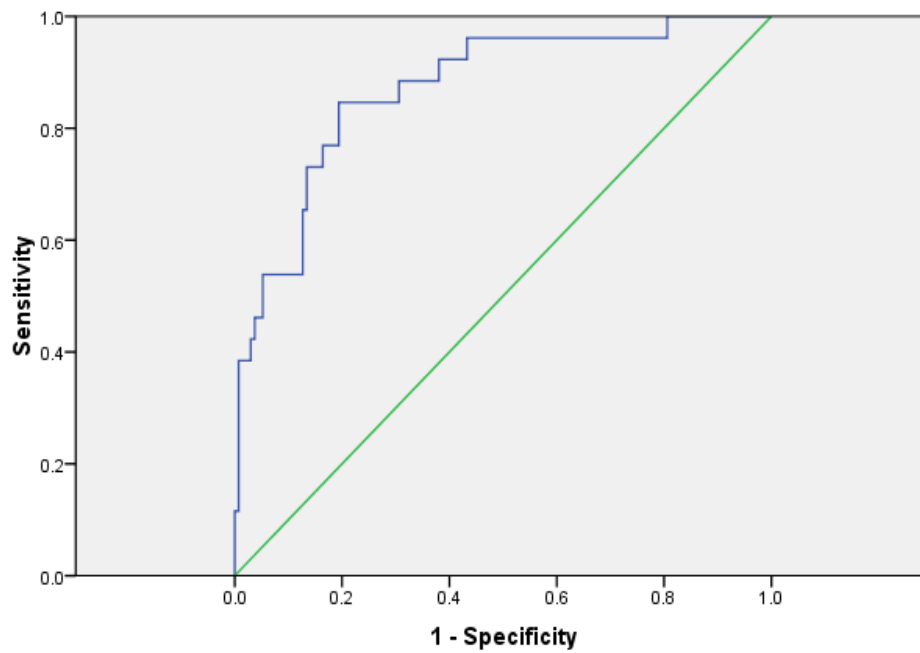


**Fig. 1.** Success rate

for different sense of coherence (SOC) tertiles at follow-up, with or without the intention to treat principle (ITT).



**Fig. 2.** Numbers needed to treat to achieve one successful lifestyle change. SOC: sense of coherence; ITT: intention to treat.



**Fig. 3.** Receiver operating characteristic curve for the variables used in the logistic regression analysis to test the predicted probability of successful lifestyle change. The area under the curve is 0.87 (95% confidence interval = 0.80–0.95).

**Table 1.** Baseline characteristics of the subjects included in the study. The values are means with standard deviations in parentheses or percentages.

	n = 213
<b>Demographics</b>	
Age (years)	46.5 (11)
Female (%)	50
Living alone (%)	26
High school or university education (%)	28
Sick leave or disabled (%)	32
Poor or very poor aerobic capacity (%)	55
<b>SF-36 HRQOL</b>	
PCS*	41 (12)
MCS**	47 (13)
<b>Clinical characteristics</b>	
Body mass index (BMI) (kg/m <sup>2</sup> )	36.8 (6.0)
Aerobic capacity (ml/kg/min <sup>2</sup> )	26.8 (7.6)
<b>Sense of coherence (SOC, n = 197)</b>	
SOC-score***	63.4 (13.6)

\*Physical component summary, \*\*mental component summary, \*\*\* sense of coherence score

**Table 2.** Odds ratios for successful lifestyle change assessed using multivariate logistic regression analysis

	<b>OR (95% CI)</b>	<b><i>p</i></b>
<b>Demographics</b>		
Age (per year)	1.00 (0.93–1.08)	0.94
Female	2.94 (0.86–10.00)	0.09
Living alone	1.97 (0.47–8.26)	0.35
Higher education	0.53 (0.12–2.32)	0.40
<b>SF-36 HRQOL</b>		
PCS* (per point)	<b>0.93 (0.86–1.00)</b>	<b>0.05</b>
MCS** (per point)	0.94 (0.88–1.01)	0.08
<b>Clinical characteristics</b>		
Body mass index (kg/m <sup>2</sup> )	1.13 (0.99–1.29)	0.07
Aerobic capacity (ml/kg/min <sup>2</sup> )	1.14 (0.98–1.31)	0.09
<b>Sense of coherence (SOC)</b>		
SOC-score*** (per point)	<b>1.21 (1.11–1.32)</b>	<b>&lt;0.001</b>
SOC-score*** (per 10 points)	<b>6.73 (2.84–16.06)</b>	<b>&lt;0.001</b>

OR: adjusted odds ratios, 95% CI: 95% confidence interval and *p* values. Bold values indicate statistically significant differences. \*Physical component summary, \*\*mental component summary, \*\*\*sense of coherence score

**Table 3.** Rate of clinically significant lifestyle change (reduced weight and increased aerobic capacity) relative to the sense of coherence (SOC) score (n = 131)

	<b>n</b>	<b><i>Success rate %</i></b>	<b><i>n</i></b>	<b><i>Success rate % ITT*</i></b>
SOC $\geq$ 30	130	20.0	196	13.3
SOC $\geq$ 40	128	20.3	186	14.0
SOC $\geq$ 50	115	21.7	161	15.5
SOC $\geq$ 60	93	26.9	121	20.7
SOC $\geq$ 70	55	41.8	72	31.9
SOC $\geq$ 80	19	57.9	23	47.8

\*Intention to treat principle used for n = 197 based on the SOC score at baseline