Effects of Telemonitoring on Heart Failure Patients' Quality of Life and Depression Scores: a Randomised Controlled Trial

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***Abstract* — Telemonitoring positively influences some aspects of quality of life. Furthermore it reduces patients' depression and anxiety scores on the short run. The current article presents the results of a one year follow-up study regarding the impact of a first generation telemonitoring system on depression and Quality of Life scores in patients with heart failure.**

Keywords - heart failure; telemonitoring; quality of life; anxiety; depression; type-D personality.

I. INTRODUCTION

Depression and impaired quality of life (QoL) are major problems in patients with heart failure, and exposure to these factors is much higher compared with a community dwelling or age-matched population [1][2][3]. Depression due to a general medical condition is defined as a patient's clinical presentation, which is dominated by a persisting mood disorder, characterized by either or both depressed mood or considerably decreased interest or pleasure in nearly all activities, or a mood that is elevated, expansive or irritable [4]. Also, other cardiac conditions, such as atrial fibrillation, are known to show elevated levels of depression and anxiety [5]. QoL is multidimensional and integrates objective and subjective indicators, a broad range of life domains, and individual values. Dimensions may be categorized in physical, material, social and emotional well being, and activity [6]. Both, depression and poor emotional QoL, can be predicted by Type-D [7][8][9]. Type-D personality is defined as 'the tendency to suppress emotional distress', and is a predictor of long-term mortality in Chronic Heart Disease (CHD), independently of established biomedical risk factors [10].

With the increased application of telemonitoring in heart failure, knowledge about its effects on QoL, and depression becomes highly important. Several telemonitoring studies reported about the impact of telemonitoring on QoL [11][12][13][14], yet limited studies reported about the impact of telemonitoring on depression in patients with heart failure [15][16]. Preliminary results, about the impact on depression, during the first 3 months of the randomized multicentre study discussed in this article (TEHAF-study), showed a tendency to a decreased level of depression [17]. The TEHAF-study primarily focuses on the effects of telemonitoring on heart failure (re)admissions and mortality [18], and cost-effectiveness [19]. Secondary outcomes are: disease specific knowledge, self-care, self-efficacy, adherence, [20] depression, and QoL. It was hypothesized that an intensive follow-up by means of telemonitoring (i.e. the Health Buddy®) improves disease specific knowledge, self-care and self-efficacy, which in turn, positively influences QoL and reduces depression and anxiety.

Several generations of telemonitoring (TM) are known. The Health Buddy® system, used in this study, is a first generation telehealth device, meaning a non-reactive data collection and analysis system. Measurements of interest are collected, and transferred to the care provider asynchronously. It is not a full telemedicine system, and the provider cannot respond immediately to patient data. Second generation systems have a non-immediate analytical or decision-making structure. Data transfer is synchronous, meaning there is some real time processing of patient data. Care providers can recognise important changes in essential measurements, but delays can occur if the systems are only active during office hours. Third generation systems provide constantly analytical and decision-making support. Such systems are used by physician led centers, staffed by specialist nurses, and have full therapeutic authority 24 h per day, seven days per week [21].

The current article presents longitudinal one-year follow-up results regarding the impact of first generation telemonitoring on depression and QoL scores, including the presence of Type-D in patients with heart failure. In the methods section the population, study design, measurement instruments, sample size and data analysis are described. Baseline patient characteristics, prevalence of type D,

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effects on QoL, anxiety and depression, and the relation between QoL, and anxiety and depression are presented in the results part, followed by the discussion, including study limitations, practical implications and conclusion.

II. METHODS

A. Population

To compare telemonitoring with usual care, 870 consecutive patients with heart failure New York Heart Association (NYHA) class II-IV were invited to participate in the TEHAF-study, during their visit at the outpatient clinic of either of three hospitals in the South of the Netherlands, of whom 488 refused or were ineligible (figure 1) flowchart). Patients were asked to fill out several questionnaires during study time [22], and were informed that refusing participation had no consequences for their further treatment. Heart failure was defined as at least, one episode of fluid retention requiring diuretics, either with an echocardiographic left ventricular ejection fraction ≤40% or a preserved ejection fraction with diastolic dysfunction.

Further inclusion criteria were age ≥18 years, capable of providing informed consent, and being treated by a heart-failure nurse together with a cardiologist. Patients were excluded if, operating the telemonitoring device i.e., the Health-Buddy®, was physically or cognitively impracticable; if suffering from Chronic Obstructive Pulmonary Disease (COPD) Gold-classification 3 or 4; if receiving hemodialysis, or in case of a disease with an expectedly shortened life span [22]. Approval was obtained from the Medical Ethical Committee of the participating centers, according to the declaration of Helsinki [23] and written informed consent was obtained before randomization. The TEHAF-study is registered as a clinical randomized controlled trial [24].

B. Study design

From October 2007 until December 2008, 382 patients were enrolled and assigned to a study arm, usual care (UC group) or usual care plus telemonitoring (TM group), using a computer-generated randomization procedure, with stratification per center. Patients of both groups received treatment according to the European guidelines [25], identical oral and written information, and had an easy access to the heart failure nurse. Patients of the UC group four, and patients of the TM group had two planned outpatient clinic visits during follow-up. Moreover, the latter group received a telemonitoring device. The Health Buddy® has a liquid crystal display and four keys and was connected to a landline phone. Every day, a preset dialogue was communicated about symptoms, knowledge and behavior, being answered by touching one of the keys.

Patients' answers were sent via a protected server to the nurses' desktop. Incorrect answers to a knowledge or behavior issue were automatically corrected by the device and visualized in the display, aiming that patients' disease knowledge would increase. Responses were transferred into risk profiles, (low, medium, high) [21] allowing the nurse to quickly identify high-risk patients. A heart failure nurse and a nurse assistant led the process. Positive answers for symptoms triggered immediate responses by the heart failure nurse. The nurse assistant was responsible for educational and general high risks, such as symptoms of depression [21]. To meet with personal specific needs on treatment or education, patients could be allocated to one of the four sets of dialogues with variable emphasis on symptoms or knowledge and behavior [20]. All patients started with the same initial set of dialogues, which was evenly balanced for symptoms and education. After three months the first evaluation of symptoms and education level occurred, with the intention to continue with the best fitting next set of dialogues. Evaluation was based on the number of high-risk alerts during the last 30 days before the end of a program. Beside this, re-allocation to maintain with the best fitting dialogues set was possible at any moment [21]. Following an admission for heart failure, patients were always re-allocated to an intensive symptom monitoring set of dialogues. Monitoring of vital signs was not part of the system.

C. Measurement instruments

Demographic variables (age, gender, race, living situation) and clinical variables NYHA functional class, left ventricular ejection fraction, ischemic heart disease, atrium fibrillation (AF), type-D personality) were measured. This article reports effects on QoL scores, measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ)[26], and depression scores, measured by the Hospital Anxiety and Depression Scale (HADS) [27]. The DS-14 consists of 14 questions, measuring negative affectivity and social inhibition. Scores ranged on a Likert scale from 0-4 points. Type D personality was indicated if both scores were equal or more than 10 points [28]. QoL was measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ). This is a 23-item questionnaire that quantifies physical limitations (question 1), symptoms (frequency [questions 3, 5, 7 and 9], severity [questions 4, 6 and 8] and recent change over time [question 2]), self-efficacy and knowledge (questions 11, 12), social interference (question 16) and QoL (questions 13–15). To facilitate interpretability, two summary scores were developed, the overall summary score (OVS) and clinical summary score (CSS), which are built up from different (sub) scores [25]. The OVS exists of the physical limitation score, total symptom score, quality of life score and the social limitation score; the CSS exists of physical limitation score and the total symptom score. The HADS, measuring anxiety and depression, is a 14 items questionnaire consisting of 7 questions for both, depression and anxiety. Scores are ranged on a 4-points Likert scale, with a total score range between 0-21 points [27]. Cut-off point for anxiety or depression disorder is 10 points and higher.

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D. Sample size

The sample size of the TEHAF-study was built on the number of hospitalizations for heart failure. Expected was a 50% reduction in heart failure admissions [22].

E. Data analysis

Demographic interval and ratio variables were investigated for normality of distribution with the Shapiro-Wilk Normality Test. If normally distributed, means and standard deviations are given. Student-t and Mann-Whitney test is used to estimate differences of baseline variables. Student-t test is also used to assess differences between AF and anxiety and depression scores, and AF and QoL. Categorical variables are presented as frequencies and percentages.

Correlations between type-D, and anxiety and depression scores or QoL, and between anxiety and depression scores and quality of life, were tested by the Pearson correlation test. Chi-square is used to assess differences for type-D personality between the usual care and telemonitoring groups. Student-t test is used to assess differences between type-D personality and QoL and depression. The effects between groups on QoL, and anxiety and depression scores in time (baseline, T3, T6, T12) were assessed with generalized estimating equations analysis (GEE).

GEE was used to correct for the dependency of the observations in time and for the difference of the time periods between the follow-up measurements. A structured covariance matrix was used in the GEE analysis.

TABLE I. BASELINE CHARACTERISTICS

Variable	N	TM group (197)	UC group (185)	*p*-value
Age (years)	382	71.0 ± 11.9	71.9 ±10.5	0.621
Range*		32-72-91	37-74-93	
≥ 75		88 (45)	85 (46)	0.199
Caucasian race		197	185	
Gender	382			0.747
Male		115 (58)	111 (60)	
Married / partner (yes)	379	122 (62)	123 (66)	0.265
Education	363			0.589
Primary school		63 (33)	59 (34)	
Secondary school /Low vocational training		91 (48)	71 (41)	
Middle Vocational training		19 (10)	23 (13)	
High vocational / university		17 (9)	20 (11)	
History of HF (months)	382	32 ±38	29 ±38	0.413
NYHA-classification / no (%)	382			0.404
NYHA II		110 (56)	109 (59)	
NYHA III		79 (40)	74 (40)	
NYHA IV		8 (4)	2 (1)	
Blood pressure (mmHg)	382			
Systolic		125 ±21.9	128 ±24.0	0.156
Diastolic		72 ±12.5	74 ±12.2	0.193
Heart rate (BPM)	382	77 ±15.1	75 ±13.8	0.252
Left Bundle Branch Block	382	20 (10.2)	22 (11.9)	0.587
Heart rhythm at baseline	382			
Sinus rhythm		96 (48.7)	113 (61.1)	0.015
Atrial fibrillation		62 (31.5)	35 (18.9)	0.007
Pacemaker rhythm		36 (18.3)	35 (18.9)	0.817
Type-D personality	360	67 (36.4)	68 (39.8)	0.358
Charlson index	382	2.6 (±1.5)	2.4 (±1.4)	0.358

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As independent variables three dummy variables for time, group (usual care versus intervention), and interaction effects between group and the dummy variables of time were included. The method of GEE is often used to analyze longitudinal and other correlated response data [29]. GEE takes into account the correlational nature of repeated measures data within subjects, and securing minimal loss of patients due to incomplete data. Data imputation is not executed because when using GEE to analyze a longitudinal dataset, imputation of missing data has no value above non-imputation [29]. Analyses were corrected for baseline differences. To analyze within group effects between baseline and after 12 months regarding QoL, anxiety and depression scores, Wilcoxon non-parametric test was used. SPSS version 18 was used for all data analyses. P-values < 0.05 were considered statistically significant.

III. RESULTS

A. Baseline characterisctics

Three hundred eighty two patients met the criteria, and were allocated to the TM group (197) or to the UC group (185). Patients' mean age was 72 (±11), and 46% were ≥75 years old; 59% were male, 65 % lived with a partner; 57% were in functional class II, 40% in Class III 3% in class IV. Mean left ventricular ejection fraction was 0.38 and 61% were ≤ 0.45; 50% had ischemic heart disease. Study arms were well balanced regarding baseline characteristics (table 1), except for AF. No differences were found for anxiety and depression, or QoL among patients with AF or other heart rhythm. Follow up was incomplete in 81 (21%), 43 in the usual-care and 38 in the intervention arm, due to death (7.8%), increasing physical impairment (6.0%), stress or losing motivation (5%), other (1%) or lost to follow-up (1.2%).

B. Prevalance of type-D personality

Respectively 184 and 176 patients answered the DS-14 questionnaire for the type-D personality. No difference in prevalence of type-D personality was found between the groups. In the TM group 67 (36.4%) and in the UC group 68 (39.8%) of the patients belongs to the category with type-D personality. Overall, no correlation was found between type-D-personality and anxiety (p=0.681, Pearson= -.022) or depression (p=0.443, Pearson=0.041) scores, whereas all dimensions of QoL (p<0.001) were negatively affected by type-D without differences between study groups.

C. Effects on anxiety and depression scores

No difference was found regarding depression prevalence at baseline, with a registration of 42% (79 on186) in the TM group and 41% (69 on 167) in the UC group. A significant difference for anxiety in favour of the TM group was found after 3 and 6 months, irrespective of correction for baseline values (Table 2). However, this effect disappeared after 12 months. For depression a significant different effect was found only after six months in favour of the TM group. After correction for the baseline values, a favourable effect was found during whole follow-up.

Also for anxiety and depression scores, within group differences were calculated among patients completing questionnaires at baseline and after 12 months. After 12 months anxiety was significantly lower in the TM group (p=0.041, Z=2.043), whereas no difference was found for and no difference for anxiety (p=0.229, Z= -1.203).

D. Effects on quality of life

Uncorrected for baseline value, the OVS and the CSS tend to differ between the TM group and the UC group after one year, yet no difference remained after correction for From patients completing the KCCQ-questionnaire at baseline and after 12 months (272) within group differences were calculated. No within group difference was found for the CSS. For OVS significantly higher score was demonstrated in the TM group (p=0.022, Z= -2. 290), whereas no difference was found for the UC group (p=0.790, Z=-.267). QoL, being a sub score of the OVS, showed similar changes, with p= 0.002 (Z= -3.149) compared to p=0.239 (Z= -1.178), respectively for the TM group and the UC group. For the sub-score self-efficacy a significant improvement was found for both groups with p<0.001 and p=0.028, respectively for the TM group and the UC group.

E. Quality of life and depression

For both groups, a negative correlation was found between the sub-score of QoL and depression (p=0.025, Pearson - 115) and QoL and anxiety (p=0.036, Pearson - .107), meaning that the presence of anxiety as well as depression is related to lower QoL. No significant correlation between anxiety and depression scores and OVS or CSS was found.

IV. DISCUSSION

In this study it was found that telemonitoring positively influences depression and anxiety scores, meaning that telemonitored patients were less depressed during whole follow-up, and less anxious at 3 and 6 months after the start of the study. The difference in depression indicates that telemonitoring seems to slightly decrease patients' moods.

Our finding of 42% depressed patients was comparable with the prevalence range of 9% to 54% in a Caucasian population as reported in a recent meta-analysis [3]. Mean depression level of all patients at baseline was slightly higher compared to the preliminary results in 101 patients investigated at 3 months after start of the study. However, the same course is demonstrated for the results after 3 months, being a slight decrease of depression scores in the

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TM group and stable level of depression scores in the UC group [17]. Initially, positive results were found for QoL, yet after correction for baseline differences disappeared.

The effects on the self-efficacy were congruent with the self-efficacy findings described elsewhere [20]. Telemonitoring improves the communication between patient and health care professional; this may result in an increased self-efficacy. The TEHAF-study primarily focused on the effects of telemonitoring on heart failure (re)admissions, mortality, and cost-effectiveness. No significant differences were found for hospitalizations and mortality, yet the number of contacts with the heart failure nurse was significantly lower for patients using telemonitoring. Sub-analysis showed differences for some sub-groups, as living with partner and heart failure duration less than 18 months [18]. No difference between groups was found for costs, however sub-group analyses showed that telemonitoring is more effective in patients with heart failure duration less than 18 months [19]. Also, a significant improvement was found for knowledge and self-care, and for some domains of adherence [20].

Myers [12] performed a non-randomised study with a follow-up time of 2 months and compared the results of 83 telemonitored patients with historical patients receiving usual care. Reported results included pre- and post-test results of the telemonitoring group, measured by the Short Form 36 item health survey (SF-36). They found an improved QoL in seven of the parameters, yet could not determine whether the change was directly related to telemonitoring. The results of the current study may considered to be due to telemonitoring because characteristics of patients were comparable, type-D personality included, and correction for baseline values was performed. Noteworthy in the study of Myers [12] was the relative high number of patients (n=19) not completing the short study in 2 months. Seven patients (37%) withdrew while they were anxious and upset, which is in contrast with our study with a withdrawal rate of 18% during the follow-up of one year. Benatar [11] followed patients for 3 months and compared the outcomes of 216 patients receiving home nurse visits versus nurse telemanagement. QoL was measured with the Minnesota Living with Heart Failure Questionnaire (MLHFQ) and depression with the HADS. They found improved QoL for both groups when compared pre- en post-intervention, yet no differences between groups. This finding implies that telemonitoring has the same effect on QoL as face-to-face contacts between patient and care professional.

Depression scores showed an improvement between groups in favour of the telemonitoring group comparable with our study results. Goldberg e.a. [30] provided 138 patients, with a mean age of 59 years (unpublished standard deviation), for 6 months with a telemonitoring system of the second generation, existing of an electronic scale and individualised questions about symptoms; almost 75% of the patients were in NYHA class III. No significant effects in QoL were measured within groups, however in the telemonitoring group QoL trended towards improvement.

No difference between groups was described. Within 48 hours post discharge, Woodend et al. [31] equipped 121 patients with heart failure with a telemonitoring system. Mean age was 66 (±11) years and most patients were in NYHA class III. The intervention consisted of 3 months video conferencing with a nurse, daily transmission of weight and blood pressure, and periodic transmission of 12-lead electrocardiogram. Measurements were performed at baseline, after 3 and 12 months. Conferences between nurse and patient were more frequent in the first few weeks after discharge. QoL was measured with the SF-36. For both groups QoL improved significantly after one year. Between groups a significant difference in favor of the videoconference group was found after 3 months, disappearing after one year. This may be interpreted as telemonitoring having effects during the monitoring time, yet effects were disappearing on the longer term. This may suggest that patients may continuously need the system to retain the effects on QoL. Unfortunately, authors did not report which care was delivered after the 3 months of videoconference, which in this context is an important issue.

The most principal differences with our study were the post discharge inclusion and the six-year younger mean age which both independently may have influenced the results. Another multi-centre randomised trial is studied [13] with a follow-up of 6 months in 315 patients. Mean age was 76.5 (±7) years and 60% were female. QoL was measured by the SF-36 and the KCCQ. No differences between groups were found for SF-36 neither for the KCCQ. Koehler [32] et al. provided 354 patients, mean age 67 (±10.7) years, with a telemonitoring device of the third generation telehealth and followed them for 24 months. They investigated QoL with the SF-36 questionnaire and depression with the Patient Health Questionnaire 9-item (PHQ9). No effects were found for depression, and an overall benefit was found for one of the QoL subscales, the first being in contrast with our effects on depression. The Whole System Demonstrator telehealth trial [33] included 1,650 patients with COPD, diabetes or heart failure in 365 general practices, in four primary care trusts in the United Kingdom. Patients were followed with second-generation telehealth devices. Measurements were performed at baseline, after 4 and 12 months. QoL was measured by the SF-12 and EQ-5D questionnaires, anxiety by the brief state-trait anxiety inventory (STAI) and depression by the center for epidemiological studies-depression scale CESD-10. Analysing the data, no disease specific distinctions were made. No differences were found for QoL, neither for anxiety or depression scores.

As mentioned earlier, the Health Buddy® system is a telemonitoring system from the first generation. Several devices belonging to the first, second and third generations are discussed above. No structurally improved effects on QoL or depression have been found in studies using higher

generation devices. Despite this is not the focus of our study, one may remark that the increased possibilities due to the evolution of telemonitoring systems has shown to lack influence regarding the effects on QoL and depression. At the other hand, underutilization of telemonitoring may occur due to a lacking clarity about the best fitting program for individual patients and equally so that the caregivers are lacking experience in using telemonitoring [34].

V. LIMITATIONS

The power of this study was calculated on a reduction of hospitalizations. Therefore, this study may be insufficiently powered to detect differences in QoL. Besides, 21% of our study population did not finish the study. The follow-up time of 12 months may be insufficient to realize improvements in QoL and depression scores. This study was performed to detect differences between groups. If within-group differences were found without significant different between groups, they are not necessarily attributable to the kind of care delivery. The use of standard questions by researchers can lead to "structural bias" and false representation, where the data actually reflect the view of the researcher instead of the participating subject [35][36][37]. Preset answers will not necessarily reflect how people really feel about a subject and in some cases might just be the closest match to preconceived hypotheses. As a consequence, the results of a quantitative questionnaire design may be statistically significant but at risk to be practically insignificant and their clinical relevance may be unclear, especially in aspects as quality of life and depression [35][36][37].

VI. PRACTICAL IMPLICATIONS OF THE STUDY

The Health Buddy® system has shown to reduce anxiety for a short term and to control depression. Therefore, it may be useful to apply telemonitoring to anxious patients to reduce anxiety and to control depression. This may particularly be meaningful for patients waiting for a referral to a professional or a mental health caregiver.

The finding that type-D personality influences QoL resonates the need of defining personality in order to detect it as a risk factor for diminished QoL [13][14][16].

Telemonitoring systems should be improved in their ability to pay attention for anxiety and depression, and integrate in depth dialogues or guidance how to deal with depressive symptoms or anxiety. This may easily enhance the positive effects of telemonitoring and alleviate the burden on patients and their environment, on health care resources and costs.

VII. CONCLUSION

The Health Buddy® system focusing on patients' experiences has proven to be suitable to positively influence some aspects of QoL, to reduce patients' depression and to reduce patients' anxiety scores in the short run. Furthermore, it was found that QoL is negatively affected by the presence of Type-D personality, and that depression and anxiety negatively affect the sub score QoL.

TABLE II. ANXIETY AND DEPRESSION SCORES

		Baseline	**3m**	**6m**	**12m**
Anxiety*					
	UC group (n= 167)	8.26	8.27	8.19	8.04
	TM group (n= 186)	7.93	7.49	7.43	7.63
	P-value	.344	.028	.028	.226
	BL-correct		.041	.053	.65
Depression*					
	UC group (n= 167)	7.11	7.12	7.28	7.66
	TM group (n=186)	6.96	6.44	6.23	6.78
	P-value	.725	.128	.030	.074
	BL-correct		.047	.011	.028

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TABLE III. QUALITY OF LIFE SCORES

		Baseline	**3 m**	**6 m**	**12 m**
Physical limitation (PLS)	UC-group (n=186)	53.9	53.7	53.6	52.4
	TM-group (n=167)	55.8	57.9	57.1	56.5
	P-value	0.533	0.148	0.230	0.189
	BL-correct		0.080	0.187	0.306
Symptom burden score (SBS)	UC-group	66.0	68.9	68.2	66.9
	TM-group	69.0	74.6	72.2	71.8
	P-value	0.233	0.019	0.130	0.076
	BL-correct		0.107	0.314	0.542
Symptom Frequency Score (SFS)	UC-group	64.5	66.6	67.7	66.0
	TM-group	66.5	72.7	69.5	69.3
	P-value	0.460	0.019	0.511	0.253
	BL-correct		0.007	0.923	0.789
Self-efficacy score (SES)	UC-group	75.7	80.5	79.5	79.1
	TM-group	80.9	85.6	86.3	85.0
	P-value	0.018	0.015	0.001	0.010
	BL-correct		0.320	0.122	0.255
Quality of life (QOL)	UC-group	58.6	64.3	63.0	60.9
	TM-group	62.8	67.6	68.5	67.8
	P-value	0.142	0.255	0.059	0.028
	BL-correct		0.997	0.247	0.177
Total symptom score (TST)	UC-group	65.2	67.1	67.9	66.4
	TM-group	67.8	73.6	70.9	70.4
	P-value	0.314	0.014	0.250	0.136
	BL-correct		0.020	0.542	0.619
Social limitation score (SLS)	UC-group	52.7	57.7	55.8	53.7
	TM-group	57.1	62.0	63.1	61.0
	P-value	0.171	0.169	0.025	0.030
	BL-correct		0.685	.0109	0.181
Overall summary score (OVS)	UC-group	57.6	60.7	60.0	58.2
	TM-group	61.0	65.2	64.7	63.8
	P-value	0.174	0.071	0.061	0.037
	BL-correct		0.238	0.164	0.208
Clinical summary score (CSS)	UC-group	59.7	61.7	62.8	62.1
	TM-group	61.9	66.8	66.3	67.4
	P-value	0.365	0.053	0.149	0.057
	BL-correct		0.015	0.303	0.394
OVS=PLS & TST & QOL & SLS					
CSS = PLS & TST					
TST = SFS & SBS					

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