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PhD THESIS

SUPPORTIVE CARE IN THE MANAGEMENT OF PATIENTS WITH HEART FAILURE AND DIABETES MELLITUS

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Limassol, 2023

Ένα καθαρό όραμα,

με την υποστήριξη ενός ξεκάθαρου σχεδίου,

δίνει στον άνθρωπο μια φοβερή αίσθηση

αυτοπεποίθησης και προσωπικής δύναμης.

Bryan Tracy

(Συγραφέας αυτοβοήθειας)

CYPRUS UNIVERSITY OF TECHNOLOGY

FACULTY OF HEALTH SCIENCES

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Supportive care in the management of patients with heart failure and diabetes mellitus

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Supportive care in the management of patients with heart failure and diabetes mellitus

by

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ABSTRACT

Introduction

Heart failure (HF) and diabetes mellitus (DM) has become a major and increasing health problem worldwide. HF and DM most of the times occur together, aggravating patients' outcomes and each disease of HFand DM independently increases the risk for the other. The growing widespread presence of patients with the comorbidity of HF and DM and the interaction of the two conditions, which is complex, the application of effective management programs is necessary, in order to improve patients' outcomes. Despite the progress in the treatment of HF and DM, the already existing management programs applied for HF population, most of them are encouraging but still, the main reason of decompensation is no adherence to the therapy and many patients feel are not supported enough. HF deteriorations lead to readmissions and the morbidity and mortality of HF patients are increased and the hazard of deterioration was found to be higher in patients with DM.

New effective approaches are necessary for improving the care, in order to minimize the burden of exacerbations and complications in HF and DM patients who have to deal everyday with various difficult and complex factors; follow a specific type of lifestyle and obtimize specific health behaviors. Patients' education only, is not effective for the development of self-care skills in the specific group of patients and this finding makes HF-DM management and supportive care that is patient-centred, based on patients' needs, complementary to ensure the best possible health related quality of life (HR-QoL). Supportive care in HF constists of four components: communication, education, psychological and spiritual issues and symptom management.

Aim

The aim of the current study was to evaluate the effectiveness of an individualized supportive care management program in patients with HF and DM, in order to improve patients' HR-QoL compared to the 'usual' care. The secondary outcomes were to investigate the difference between HF-DM patients receiving the supportive care interventions and 'usual' care, in terms of self-management, knowledge, perceived social support, exercise tolerance, anxiety and depression, acute events and mortality.

Study design

The current study, is a sub-analysis of the randomized clinical trial (RCT) named 'SupportHeart' (Trial ID: NCT04415723) using pragmatic methodology. It was consisted by two groups: 1. The control group (CG) and 2. The intervention group (IG). The study investigated the patients for a period of one year at 5 time points (in baseline, 1 month, 3 months, 6 months, 1 year). The study development of the RCT 'SupportHeart' followed the steps below:

1. The first step was the conduction of a qualitative research (Metasynthesis) in order to determine what HF (and DM) patients describe as major needs and which intervention was effective for them. The support needs extracted, served as a 'guide' to develop a plan to be used in the intervention.

2. Focus groups exploring patients with HF views on their support needs were also conducted, to find out, if the literature reflects their needs or if specific aspects for their support needs are missing. The most important aspects of care were identified by patients' questions. Results of the focus groups were used to create the educational program for the IG. Self-management, palliative care, supportive care, social support, patient - centred care and better health care services were the themes developed from the sub-themes of the focus groups. The Colaizzi's phenomenological method of analysis of the qualitative data was performed, to identify themes grounded in the responses.

3. Findings excracted from the focus groups used as a guide for the 'SupportHeart' research team to deliver the intervention program, based on the four components of supportive care; communication, education, psychological & spiritual issues and symptom management.

4. The quantitative phase of data collection followed, using the following tools: the Greek versions of the 'Minnesota Living with Heart Failure questionnaire' (MLHFQ), the 'Self-care of Heart Failure Index' (SCHFI), the 'Multidimensional scale of perceived social support'(MSPSS), the 'European Heart Failure Self-Care Behavior Scale' (Gr9EHFScB), the 'Hospital and Anxiety depression scale' (HADS), the 'International Physical Activity Questionnaire' (IPAQ), the 'Audit of Diabetes Dependency Quality of Life Version 19' (ADDQoL-19), socio-demographic and clinical variables of the participants.

Descriptive statistics were used to present the results of the quantitative analysis. Baseline characteristics were compared using independent samples Welsch t-test when the variables were continuous (e.g. age, HbA1c) and the Fisher's exact test in the case of categorical variables (e.g. gender, comorbidity, etc.). Comparisons between IG and CG at each time point were assessed using a Welsch t-test. Comparisons of lost to follow- up between the two groups, as well as the comparisons of the number of acute events between the two groups were assessed using the Fisher's exact test. For the effect of the intervention on the Scales' scores (e.g. MLHFQ, ADDQoL, HADS, etc.) Linear Mixed Models Effects (LMME) were performed with the level of the scale as the dependent variable, and independent variables the group (CG, IG), the time-point (baseline, 1 month, 3 months, 6 months, 1 year) and the interaction between group and time-point (Group X Time). The models were also adjusted by the age, sex, NYHA classification, HbA1c level, etc. of the participants. Reliability of the scales was measured using the internal consistency index of Cronbach's alpha. Cronbach's alpha values greater than (>) 0.70 are considered satisfactory.

Results

The sample consisted of 121 patients (N=56 in the IG and N=65 in the CG), with HF and DM, 80 (66%) male and 41 (34%) female patients. All patients had DM2. The mean age of the patients was $\bar{x}$ =73.9 (SD = 9.1) years old. Most of the patients were married (55%) and 33% were widowers. Regarding the educational level 56 (46%), 45 (37%) and 11 (9.1%) patients had elementary, secondary and higher education, respectively. There were no patients at NYHA stage I in the current study but most of them [69 (57%)], were classified at NYHA stage III [CG 35 (54%) and IG 34 (61%)] (p= 0.2). The majority of the participants [(N = 91 (75%)] had the underlying disease of CAD, 35 (29%) had acute arrhythmias, and 22 (18%) had chronic atrial fibrillation. The most frequent risk factor from the clinical characteristics was hypertension [94 (78%)], with higher incidence in the CG [56(86 %)] compared with the IG [38(68%)] (p= 0.016). The second more frequent co-existing risk factor was hyperlipidemia which was present in 74 patients with the higher incidence in the IG [37 (66%)] compared with the CG [37 (57%)] (p=0.3). The third risk factor was obesity [19 (16%)] with higher incidence in the CG [11 (17%)] compared with the IG [8 (14%)] (p= 0.7).

In the current study, the multilevel model for the effect of the intervention on HR-QoL has shown a statistically significant effect of the IG at all time points after the intervention ($p < 0.001$) on the overall HR- QoL. The Linear Mixed Model results have shown that there is a statistically significant effect in the IG at all time points after the intervention ($p < 0.001$) in all the dimension of MLHFQ; physical, emotional and social HR-QoL. The IG had higher perceived social support compared to the CG ($p<0.001$) at all dimensions of the MSPSS at first month, three months, six months and in one year after the intervention. At three months after the intervention, six months, and in one year the IG had lower emotional distress compared to the CG. At one year after the intervention $p<0.001$ in all the dimensions of the HADS. The multilevel model for the effect of the intervention on the HADS in the overall emotional distress and the Linear Mixed Model results, did not show any statistically significant effect of the intervention, at any of the time points after the intervention ($p > 0.05$) at the dimension of anxiety and at the dimension of depression ($p= 0.004$), but clinically there was a declining trend in almost at all time points after the intervention. The Linear Mixed Model results have shown that there was a statistically significant effect of the intervention at all the time points after the intervention ($p < 0.001$) in all the dimensions of the SCHFI; the maintenance, management and self-confidence dimension. The multilevel model analysis for the effect of the intervention on the total self-care score for the GR9EHFScBS showed a statistically significant effect of the intervention at all the time points after the intervention ($p < 0.001$) in the overall self-care. At three months, six months and one year after the intervention, the IG showed more overall physical activity compared to the CG ($p<0.001$), and specifically higher walking ($p < 0.001$) and moderate exercise ($p < 0.001$). The multilevel model for the effect of the intervention on physical activity did not show a statistically significant effect of the intervention at any time point ($p > 0.05$) for the overall physical activity. Patients in the IG experienced better HR-QoL related to DM, in the dimensions of ADDQoL ($p <0.001$) and DM was not found to affect their HR-QoL. The level of glycosylated haemoglobin (HbA1c) showed that the patients in the IG had significally lower values across time, compared to CG ($p <0.001$) where the levels of HbA1c from 7.1 % (0.5) at baseline falls to 6.9% (0.4) in one year, and in the CG was 7.5% (0.7) at baseline and falls to 7.4% (0.6) in a year. In survival analysis both acute events (readmissions / emergency room visits) and mortality, after three months and until six month time point, in the CG [9/58 (15.5 %)] were observed more acute events and deaths compared to the IG [1/49 (2%)] (p=0.02)].

Discussion/ Conclusion

Supportive care seems to be a promising concept for HF-DM management programs. The pragmatic methodology that used in the current sub -analysis reseach study has an intensive intervention which started rapidly and in early stages, based on patient –centred quidelines, focused on the ‘real world’ and on the ‘real needs’ of HF-DM patients and was rapidly accepted by the patients in the IG since it improved their HR-QoL symptoms and acute events. Future studies should be focused on the specific population of HF-DM patients and access and apply supportive care management programs in a long-term duration for this population, with the scope to icrease their HR-QoL, reduce acute events and make patients actively participants in the management of their own chronic conditions in a continues and long-term support.

Keywords

Supportive care, health-related quality of life, heart failure, diabetes mellitus, person-centred care, heart failure-diabetes mellitus management programs.

ΠΕΡΙΛΗΨΗ

Εισαγωγή

Η καρδιακή ανεπάρκεια (ΚΑ) και ο σακχαρώδης διαβήτης (ΣΔ) αποτελούν μείζον και αυξανόμενο πρόβλημα υγείας παγκοσμίως. Η ΚΑ και ο ΣΔ τις περισσότερες φορές συνυπάρχουν, επιδεινώνοντας τις εκβάσεις των ασθενών και η νόσος της ΚΑ και του ΣΔ αυξάνουν τον κίνδυνο ανεξάρτητα η μια από την άλλη. Η όλο και αυξανόμενη συννοσυρότητα της ΚΑ και του ΣΔ καθώς κα η αλληλεπίδραση των δύο ασθενειών που είναι πολύπλοκη, καθιστούν απαραίτητη την εφαρμογή αποτελεσματικών προγραμμάτων διαχείρισης για τη βελτίωση των εκβάσεων των ασθενών. Παρά τη πρόοδο στις θεραπείες για τη ΚΑ και το ΣΔ τα ήδη υπάρχουσα προγράμματα που εφαρμόζονται σε ασθενείς με ΚΑ είναι ενθαρυντικά, αλλά ο κυριότερος λόγος αντιστάθμισης είναι η μη συμμόρφωση προς τη θεραπεία και οι περισσότεροι ασθενείς νιώθουν πως δεν παίρνουν την απαραίτητη υποστήριξη. Η επιδείνωση της ΚΑ οδηγεί σε επανεισαγωγές και η νοσηρότητα και θνησιμότητα των ασθενών με ΚΑ ολοένα και αυξάνεται με τον μεγαλύτερο κίνδυνο επιδείνωσης σε ασθενείς με ΣΔ.

Νέες αποτελεσματικές προσεγγίσεις είναι απαραίτητες για τη βελτίωση της παρεχόμενης φροντίδας, για τη μείωση του κινδύνου επιδείνωσης και των επιπλοκών σε ασθενείς με ΚΑ και ΣΔ οι οποίοι πρέπει καθημερινά να διαχειριστούν διάφορα δύσκολα και περίπλοκα ζητήματα; να ακολουθούν συγκεκριμένο τρόπο ζωής και να επικεντρώνονται σε συγκεκριμένες συμπεριφορές σχετιζόμενες με την υγεία. Μόνο η εκπαίδευση των ασθενών δεν είναι αποτελεσματική για την απόκτηση δεξιοτήτων αυτοδιαχείρισης της συγκεκριμένης ομάδας ασθενών και αυτό το εύρημα καθιστά τη διχείριση της ΚΑ και του ΣΔ και την υποστηρικτική φροντίδα με επίκεντρο τους ασθενείς που να βασίζεται στις ανάγκες τους, απαραίτητη για τη διαβεβαίωση της καλύτερης σχετιζόμενη με την υγεία ποιότητα ζωής (ΣΥΠΖ). Η υποστηρικτική φροντίδα στη ΚΑ, αποτελείται από τέσσερα διαφορετικά στοιχεία: επικοινωνία, εκπαίδευση, ψυχολογικά και πνευματικά θέματα και αυτοδιαχείριση των συμπτωμάτων.

Σκοπός

Σκοπός της παρούσας μελέτης είναι η αξιολόγηση της αποτελεσματικότητας ενός εξατομικευμένου υποστηρικτικού προγράμματος διαχείρισης ασθενών με ΚΑ και ΣΔ

σε σχέση με τη βελτίωση της ΣΥΠΖ, συγκριτικά με τη «συνήθη φροντίδα». Οι δευτερεύουσες εκβάσεις αποτελούν τη διερεύνηση της διαφοράς μεταξύ ασθενών με ΚΑ και ΣΔ που λαμβάνουν τις παρεμβάσεις της υποστηρικτικής φροντίδας και της «συνήθης θεραπείας» όσο αφορά την αυτοδιαχείριση, τη γνώση, την αντιλαμβανόμενη κοινωνική υποστήριξη, την αντοχή στην άσκηση, το άγχος και την κατάθλιψη, τα οξέα συμβάντα και την θνησιμότητα.

Σχεδιασμός της μελέτης

Η παρούσα μελέτη αποτελεί μελέτη υπο-ανάλυσης της Τυχαιοποιημένης Κλινικής Δοκιμής (ΤΚΔ) ‘SupportHeart’ (Trial ID: NCT04415723) με τη χρήση της διερευνητικής μεθοδολογίας σε δύο ομάδες: 1.ομάδα ελέγχου (ΟΕ) και 2. ομάδα παρέμβασης (ΟΠ). Στη μελέτη διερευνήθηκαν οι ασθενείς για τη χρονική περίοδο του ενός έτους σε πέντε διαφορετικές χρονικές περιόδους (στη βασική γραμμή, σε 1 μήνα, σε 3 μήνες, σε 6 μήνες και σε 1 χρόνο). Ο σχεδιασμός της ΤΚΔ ‘SupportHeart’ ακολούθησε τα πιο κάτω βήματα:

1.Συστηματική ανασκόπηση και μετα-σύνθεση. Η μετα-σύνθεση πραγματοποιήθηκε για να προσδιορίσει τις αναφερόμενες ως υποστηρικτικές ανάγκες των ασθενών με ΚΑ (και ΣΔ) για να προσδιορίσει ποιες παρεμβάσεις υποστηρικτικής φροντίδας ήταν αποτελεσματικές, προκειμένου να συμπεριλαμβάνονται στα προγράμματα διαχείρισης.

2. Ομάδες εστίασης οι οποίες πραγματοποιήθηκαν για να εξερευνήσουν τις ανάγκες των Κυπρίων ασθενών για να προσδιορίσουν εάν η βιβλιογραφία αντικατοπτρίζει τις ανάγκες τους ή εάν λείπουν συγκεκριμένοι τομείς. Τα περισσότερα στοιχεία εντοπίστηκαν από τις ερωτήσεις των ασθενών. Τα αποτελέσματα χρησιμοποιήθηκαν για τη δημιουργία του εκπαιδευτικού προγράμματος της ΟΠ. Τα θέματα τα οποία αναδείχθηκαν από τις ομάδες εστίασης ήταν τα ακόλουθα: η αυτοδιαχείρηση, η παρηγορητική φροντίδα, η υποστηρικτική φροντίδα, η κοινωνική υποστήριξη, η φροντίδα με επίκεντρο τον ασθενή και η καλύτερη παροχή υπηρεσιών υγείας. Για την ανάλυση των ποιοτικών δεδομένων χρησιμοποιήθηκε η φαινομενολογική προσέγγιση κατά Colaizzi.

3. Τα ευρήματα από τις ομάδες εστίασης χρησιμοποιήθηκαν από την ερευνητική ομάδα του «SupportHeart» για να εφαρμοστούν στο παρεμβατικό πρόγραμμα για την ΟΠ,

βασισμένο στα τέσσερα στοιχεία της υποστηρικτικής φροντίδας: εποικοινωνία, εκπαίδευση, ψυχολογικά και πνευματικά θέματα και διαχείρηση των συμπτωμάτων.

4.Στη συνέχεια ακολούθησε η ποσοτική ανάλυση των δεδομένων με τη χρήση των πιο κάτω εργαλείων: οι Ελληνικές εκδόσεις των ‘Minnesota Living with Heart Failure questionnaire’ (MLHFQ), ‘Self-care of Heart Failure Index’ (SCHFI), ‘Multidimensional scale of perceived social support’ (MSPSS), ‘European Heart Failure Self-Care Behavior Scale’ (Gr9EHFScB), ‘Hospital and Anxiety depression scale’ (HADS), ‘International Physical Activity Questionnaire’ (IPAQ), ‘Audit of Diabetes Dependency Quality of Life Version 19’ (ADDQoL-19), κοινωνικο-δημογραφικά στοιχεία και κλινικές μεταβλητές των συμμετεχόντων.

Χρησιμοποιήθηκε η περιγραφική στατιστική για τη παρουσίαση των αποτελεσμάτων της ποσοτικής ανάλυσης. Τα χαρακτηριστικά της βασικής γραμμής συγκρίθηκαν χρησιμοποιώντας ανεξάρτητα δείγματα Welsch t-test για τις συνεχείς μεταβλητές (π.χ. ηλικία, HbA1c) και το τεστ Fisher’s exact στην περίπτωση των κατηγορικών μεταβλητών (π.χ. το φύλο,οι συννοσυρότητες κλπ). Οι συγκρίσεις μεταξύ της ΟΠ και της ΟΕ για κάθε χρονική περίοδο έγινε με τη χρήση του Welsch t-test. Οι συγκρίσεις των συμμετεχόντων που αποχώρησαν/χάθηκαν μεταξύ των δύο ομάδων καθώς και των αριθμών των οξέων συμβάντων ανάμεσα στις δύο ομάδες έγινε με τη χρήση του Fisher’s exact test. Για την επίδραση της παρέμβασης στις κλίμακες (π.χ. MLHFQ, ADDQoL, HADS, κ.λ.π) χρησιμοποιήθηκαν τα μοντέλα Linear Mixed Models Efects (LMME) με τα επίπεδα των κλιμάκων ως εξαρτημένες μεταβλητές, και ως ανεξάρτητες μεταβλητές τις ομάδες (ΟΕ, ΟΠ), τις 5 χρονικές περιόδους και για την αλληλεπίδραση μεταξύ των δύο ομάδων και για τη χρονική περίοδο (Group X Time). Τα μοντέλα επίσης προσαρμόστηκαν σε σχέση με την ηλικία, το φύλο, την ταξινόμηση κατά NYHA, τα επίπεδα της HbA1c κλπ. Η αξιοπιστία των κλιμάκων μετρήθηκε με τη χρήση του δείκτη εσωτερικής συνέπειας Cronbach’s alpha.Οι τιμές του Cronbach’s alpha μεγαλύτερες από (>) 0.70 θεωρούνται ικανοποιητικές.

Αποτελέσματα

Το δείγμα αποτελούσαν 121 ασθενείς (N=56 ΟΠ και N=65 ΟΕ), με ΚΑ και ΣΔ, 80 (66%) άντρες και 41 (34%) γυναίκες. Όλοι οι ασθενείς ήταν με σακχαρώδη διαβήτη τύπου 2 (ΣΔ2). Η μέση ηλικία των ασθενών ήταν $\bar{x}$ =73.9 (SD = 9.1). Οι περισσότεροι ήταν παντρεμένοι (55%) και 33% ήταν χήροι. Όσον αφορά το επίπεδο εκπαίδευσης, 56 (46%), 45 (37%) and 11 (9.1%) ασθενείς ήταν απόφοιτοι κατώτερης, μέσης και ανώτερης εκπαίδευσης αντίστοιχα. Στο δείγμα δεν υπήρχε κανένας ασθενής σε επίπεδο NYHA I, με τους περισσότερους [69 (57%)] στο επίπεδο NYHA III [ΟΕ 35 (54%) και ΟΠ 34 (61%)] (p= 0.2). Οι περισσότεροι από τους συμμετέχοντες [N = 91 (75%)] είχαν υποκείμενο νόσημα τη στεφανιαία νόσο, 35(29%) τις οξείες αρρυθμίες και 22 (18%) την χρόνια κολπική μαρμαρυγή. Ο πιο συχνός παράγοντας κινδύνου ήταν η υπέρταση [94 (78%)], με την ψηλότερη συχνότητα στην ΟΕ [56(86 %)] σε σύγκριση με την ΟΠ [38(68%)] (p= 0.016). Ο δεύτερος παράγοντας κινδύνου ήταν η υπερλιπιδαιμία σε 74 ασθενείς με την ψηλότερη συχνότητα σε ασθενείς της ΟΠ [37 (66%)] σε σύγκριση με την ΟΕ [37 (57%)] (p=0.3). Ο τρίτος παράγοντας κινδύνου ήταν η παχυσαρκία [19 (16%)] με την μεγαλύτερη συχνότητα στην ΟΕ CG [11 (17%)] σε σύγκριση με την ΟΠ [8 (14%)] (p= 0.7).

Στη παρούσα μελέτη, το πολυπαραγοντικό μοντέλο για την επίδραση της παρέμβασης στη ΣΥΠΖ έδειξε σημαντική στατιστική διαφορά της ΟΠ σε όλα τα χρονικά σημεία μετά την παρέμβαση (p ‹ 0.001) στο σύνολο. Το μοντέλο Linear Mixed Model έδειξε επίσης σημαντική στατιστική διαφορά της ΟΠ σε όλα τα χρονικά σημεία μετά την παρέμβαση (p ‹ 0.001) σε όλες τις διαστάσεις του MLHFQ; τη φυσική, τη συναισθηματική και τη κοινωνική ΣΥΠΖ. Η ΟΠ είχε μεγαλύτερη αντιλαμβανόμενη κοινωνική υποστήριξη σε σύγκριση με την ΟΕ (p<0.001) σε όλες τις διαστάσεις του MSPSS τον πρώτο μήνα, στους τρεις μήνες, στους έξι μήνες και στον ένα χρόνο μετά την παρέμβαση. Στους τρεις μήνες μετά την παρεμβαση, στους έξι μήνες και στον ένα χρόνο η ΟΠ είχε χαμηλότερη συναισθηματική δυσφορία σε σύγκριση με την ΟΕ. Στον ένα χρόνο μετά την παρέμβαση p<0.001 σε όλες τις διαστάσεις του HADS σε χέση με την συναισθηματική δυσφορία. Το πολυπαραγοντικό μοντέλο για την επίδραση της παρέμβασης του HADS στη συνολική συναισθηματική δυσφορία και το μοντέλο Linear Mixed Model, δεν έδειξε καμία στατιστική σημαντικότητα της παρέμβασης σε καμία από τις χρονικές περιόδους μετά την παρέμβαση (p > 0.05), στις διαστάσεις του άγχους και της κατάθλιψης ($p = 0.004$) παρόλο που έδειξε πως κλινικά υπήρχε μείωση και στις δύο διαστάσεις μετά την παρέμβαση σε όλες σχεδόν τις χρονικές περιόδους. Το μοντέλο Linear Mixed Model έδειξε σημαντική στατιστική διαφορά μετά την παρέμβαση ($p < 0.001$) σε όλες τις διαστάσεις του ερωτηματολογίου SCHFI. Το πολυπαραγοντικό μοντέλο ανάλυσης για την επίδραση της παρέμβασης στην αυτο-φροντίδα για το ερωτηματολόγιο GR9EHFScBS έδειξε σημαντική στατιστική διαφορά της παρέμβασης σε όλες τις χρονικές περιόδους μετά την παρέμβαση ($p < 0.001$) στην ολική αυτό-φροντίδα. Στους τρεις μήνες, στους έξι μήνες και στον ένα χρόνο μετά την παρέμβαση, η ΟΠ έδειξε περισσότερη συνολική φυσική δραστηριότητα σε σύγκριση με την ΟΕ ($p<0.001$), και ειδικά στο επίπεδο ψηλής έντασης περπάτημα ($p < 0.001$) και στη μέτρια έντασης άσκηση ($p < 0.001$). Το πολυπαραγοντικό μοντέλο για την επίδραση της παρέμβασης στη φυσική δραστηριότητα δεν έδειξε σημαντική στατιστική διαφορά της παρέμβασης σε καμία χρονική περίοδο ($p > 0.05$) στη συνολική φυσική δραστηριότητα. Οι ασθενείς της ΟΠ έδειξαν καλύτερη ΣΥΠΖ σε σχέση με το ΣΔ, στις διαστάσεις του ADDQoL (p ‹0.001) και ο ΣΔ δεν φάνηκε να επηρεάζει την ΣΥΠΖ τους. Σε σχέση με τα επίπεδα της γλυκοζηλιωμένης αιμοσφαιρίνης (HbA1c) οι ασθενείς στην ΟΠ έδειξαν στατιστικά σημαντικά χαμηλότερες τιμές διαχρονικά, σε σχέση με την ΟΕ (p ‹0.001) όπου τα επίπεδα της HbA1c από 7.1 % (0.5) στην βασική γραμμή μειώθηκαν στο 6.9% (0.4) σε ένα χρόνο και στην ΟΕ ενώ ήταν στο 7.5% (0.7) στη βασική γραμμή μειώθηκαν στο 7.4% (0.6) σε ένα χρόνο. Στην ανάλυση επιβίωσης τόσο τα οξέα συμβάντα (επανεισαγωγές/επισκέψεις στα τμήματα επειγόντων περιστατικών) και η θνησιμότητα, από τρεις μέχρι έξι μήνες, στην ΟΕ [9/58 (15.5 %)] παρατηρήθηκαν περισσότερα οξέα συμβάντα και θανάτοι σε σύγκριση με την ΟΠ [1/49 (2%)] ($p=0.02$)].

Συζήτηση/Συμπεράσματα

Η υποστηρικτική φροντίδα φαίνεται να αποτελεί μια έννοια αρκετά υποσχόμενη για τα προγράμματα διαχείρισης της ΚΑ και του ΣΔ. Η διερευνητική μεθοδολογία που χρησιμοποιήθηκε στην παρούσα ερευνητική μελέτη υπο-ανάλυσης, εφάρμοσε μια εντατική παρέμβαση η οποία άρχισε νωρίς, βασισμένη στη προέγγιση με επίκεντρο τους ασθενείς, σε ένα «πραγματικό κόσμο» και σε «πραγματικές ανάγκες» των ασθενών με ΚΑ και ΣΔ και αυτή η προσέγγιση έγινε γρήγορα αποδεκτή από τους ασθενείς της ΟΠ αφού βελτίωσε τη ΣΥΠΖ τους και τα οξέα συμβάντα. Οι μελλοντικές

έρευνες θα πρέπει να ασχοληθούν με τον συγκεκριμένο πληθυσμό των ασθενών με ΚΑ και ΣΔ και να αξιολογήσουν την εφαρμογή προγραμμάτων διαχείρισης βασισμένα στην υποστηρικτική φροντίδα με μακροπρόθεσμη διάρκεια, με στόχο την βελτίωση της ΣΥΠΖ, τη μείωση των οξέων συμβάντων με την ενεργή συμμετοχή των ασθενών στη διαχείριση της δικής τους κατάστασης με συνεχιζόμενη και μακροπρόθεσμη υποστήριξη.

Λέξεις-Κλειδιά

Υποστηρικτική φροντίδα, σχετιζόμενη με την υγεία ποιότητα ζωής, φροντίδα με επίκεντρο τον ασθενή, προγράμματα διαχείρισης καρδιακής ανεπάρκειας -σακχαρώδη διαβήτη.

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LIST OF ABREVIATIONS

HF	Heart failure
DM	Diabetes mellitus
HR-QoL	Health related quality of life
CV	Cardiovascular
DM2	Diabetes mellitus type 2
CVD	Cardiovascular disease
NYHA	New York Heart Association
DMCM	Diabetes mellitus cardiomyopathy
LVEF	Left-ventricular ejection fraction
HFrEF	Heart failure reduced ejection fraction
HFmEF	Heart failure with mid-range ejection fraction
HFpEF	Heart failure preserved ejection fraction
HbA1c	Glycosylated haemoglobin
PPARs	Proliferator - activated receptors
HDL	High Density Lipoprotein
LDL	Low Density Lipoprotein
DPP- 4	The dipeptidyl peptidase-4
GLP-1RAs	Peptide-1 receptor agonists
SGLT-2i	Sodium-glucose cotransporter-2 inhibitors
DHT	Digital health technology
HPs	Health professionals'
NHS	National Health Care System
MI	Motivational interviewing

CPCC	Continuing person-centred care
MLHFQ	Minnesota Living with Heart Failure Questionnaire
SCHFI	Self-care of Heart Failure Index
MSPSS	Multidimensional scale of perceived social support
Gr9-EHFScBS	European Heart Failure Self-Care Behavior Scale
HADS	Hospital and Anxiety depression scale
IPAQ	International Physical Activity Questionnaire
ADDQoL	Audit of Diabetes Dependency Quality of Life
CAD	Coronary artery disease

GENERAL SECTION

1.INTRODUCTION

This chapter presents the background of the current study, examining the prevalence of heart failure (HF) and diabetes mellitus (DM). HF with the commorbidity of DM influence significantly the lives of patients affecting their health related quality of life (HR-QoL) and their ability to maintain self-care management. A qualitative research (Metasynthesis) that has been conducted to meet the needs of the patients with HF will be presented, including details of the work that provide evidence to underpin the development of the intervention (Kyriakou et al., 2019). A systematic review has also been conducted to identify the factors influencing adherence to the therapy of patients with HF and DM and is presented in this section. This intervention progam designed to provide support and encouragement to HF-DM patients, promote healthy behaviors like treatment control, proper diet, physical activity and mobility and it highlights the need for self-management.

1.1 Overview of heart failure and diabetes mellitus condition

D.M is a crucial population health issue and more than 400 million adults globally diagnosed with DM. HF is related to cardiovascular (CV) morbidity and mortality in DM and especially in diabetes mellitus Type 2 (DM2) is found to rise up to 28% (Shah et al, 2015). Furthermore, HF and DM, have a higher risk of hospitalization due to HF and CV death compare with patients with either one of the diseases alone *(*McAllister et al, 2018).

HF has been mentioned as the most malignant type of cardiovascular disease (CVD) and has the same aggravation of symptoms and survival rates, as the most types of cancer (Mamas et al. 2017, Forsyth et al. 2019). It is a syndrome characterized by symptoms that persist; breathlessness, fatigue and swelling of ankles. All these symptoms affect the HR-QoL and the ability of the patients to maintain self-care management (Cleland et al. 2019, Koshy et al. 2020, McDonagh et al. 2021).

Despite the progress in the treatment of HF, HF deteriorations lead to readmissions and the morbidity and mortality of HF patients are increased and the hazard of deterioration was found to be higher in patients with DM (Lambrinou et al., 2020). The findings in the MEETinCY trial highlighted there is a need for more investigations and a need to offer supportive programs to minimize the risk of acute events in HF and especially in patients with HF and DM (Lambrinou et al., 2020). HF is the first reason for hospital admission in patients over 65years old and the costs for the hospitalization represent a major financial issue (Parissis et al., 2015). The associated comorbidities of HF like DM, not only contribute to the progression of the disease and to higher hospitalization, but they also increase the costs of hospitalization (Beller et al. 2001, Stewart et al. 2002, Filippatos et al. 2014). Beller (2001) refers to DM as the largest comorbidity of HF patients that affects negatively the outcomes of the CVD. Einarson et al. (2018) and Gulsin et al. (2019), refer that HF in diabetic patients is an important health problem and DM is a major risk factor in HF and vice versa. HF and DM most of the times occur together, aggravating each condition and exacerbates patient outcomes (Randhawa et al. 2021, Park 2021).

There are more than 415 million people with DM globally nowadays and is expected that, more than 592 million people will develop diabetes by the year 2035 (Guariguata et al. 2014, Reddy et al. 2018). It is considered that between HF patients, the prevelence of DM is 2 to 2.5 times higher than in the general population (Cha et al., 2011). DM2 is often a disease due to the modern lifestyle, but also a disease of genetic predisposition (King et al., 1998). Many clinical studies show that DM2 breed HF and vice versa (Aroor et al., 2012)

Observational studies in HF with DM found that there is a strong relationship between glycaemic control and clinical outcomes that affect negatively the HR-QoL (Ahmed et al. 2006, MacDonald et al. 2008, Aquilar et al. 2010). Adhererence and management of the two conditions by patients with HF and DM to follow a low- sodium diet, monitor weight, daily fluid volume, breath more effectively such as folow coughing techniques, quit smoking, manage fatigue, manage normal glucose levels, coping with stress, follow medication adherence, be physical active, socialize, manage relax and early detection of decompensation signs, are difficult.

The New York Heart Association (NYHA) functional classification system for the severity of symptoms, staged HF as: Stage I (no physical limitation), Stage II (slight limitation of physical activity in the form of moderate exertion), Stage III (marked limitation of physical activity in the form of minimal exertion) and Stage IV (inability to exert because of symptoms of HF at rest). Further the NYHA, staged HF as extended by stage A (at-risk persons with DM), stage B (DM cardiomyopathy [DMCM] without HF), stage C (DMCM with HF), and stage D (refractory HF from end-stage DMCM) (Greene et al. 2018, Cosentino et al. 2019). HF can also be more categorized by left-ventricular ejection fraction (LVEF), as reduced (HFrEF, LVEF≤ 40%), mid-range (HFmEF, LVEF 41%-49%), or preserved (HFpEF, LVEF ≥50%) (Greene et al. 2018, Cosentino et al. 2019).

One of the common reasons of decompensation in HF is poor self- management (Clark et al., 2008). Davis et al. (2015) have found that chronic diseases have important health and care cost to both; patients and health care system. Effective approaches are necessary for improving the care in order to minimize the burden of exacerbations and complications especially in patients with HF and DM, since patients have to manage two complex conditions (Krause et al. 2014, Sharma et al. 2019). Patients with HF and DM have to deal everyday with various difficult and complex factors; follow a specific type of lifestyle and obtimize specific health behaviors eg. , physical activity, more complex diet, blood glucose checking, daily weight and adherence to complex medications for both diseases, which may interact with each other causing serious side effects to the patients, as well as they deal with acute and chronic complications of HF or DM (Sharma et al., 2019). Most of the times, patients' education is not effective for the development of self-care skills in patients with HF and DM and their caregivers (Clark et al., 2009). So, it makes necessary to find more effective ways of coping for patients, family and caregivers (Gallagher et al., 2011). Treatments, such as medication and behavior change have a major role in maintaining physiological stability and are crucial in obstructing episodes of decompensation and re-hospitalization in HF patients with DM (Paradis et al., 2010).

The nature of HF and DM makes advanced HF-DM management and supportive care complementary. The chronic and life-limiting aspects of HF-DM require supportive care: patient-centred care that integrates patient preferences and patient and family needs into the goals of care, manages symptoms to the level of comfort desired, and attempts to reduce the burden of illness for both the patient and his family (Goodlin et al. 2004, Kyriakou et al. 2020). Supportive care is a multidisciplinary holistic care provided in both, the patient and his family, since the time of the diagnosis along with the treatment aiming to prolong life and into the end of life with palliative care (Ahmedzai et al. 2005, Kyriakou et al. 2019, Kyriakou et al. 2020).

Self-management support programs through motivational interviewing (MI) seem to be an effective method to change the patients' behavior (Rubak et al., 2013). In the current study, MI was used in an effort to apply a person-centred care approach and continuing communication with the patients. MI is defined as an evidence-supported collaborative and person-centred plan of guidance to extract and strengthen motivation for change (Rubak et al., 2013). Behavior improvement lead to better disease control and better outcomes, such as reduced utilization of health care services, emergency room visits and hospitalizations (Pearson et al. 2007, Rubak et al. 2013).

The current study is the first study that introduce a supportive care management program to patients with HF and DM focusing on patient - centred approach. Supportive care is the multi-disciplinary holistic care of patients with malignant and non-malignant chronic diseases and serious illness, and those that matter to them, to ensure the best possible HR-QoL (Beattie and Goodlin 2008, Fendler et al. 2015). It extends as a right and necessity for all patients, is available throughout the course of the condition, concurrent to condition management and is given equal priority alongside diagnosis and treatment. It should be individualized, considering the patient's past life experiences, their current situation and personal goals (Cramp and Bennett, 2013). The proposed study examines how an individualized supportive management program affects the patient in four components that are part of the supportive care: 1. Communication, 2. Education, 3. Psychological and Spiritual issues and 4. Symptom management (Goodlin et al., 2009).

A nurse-led management program which includes supportive care through the empowerment of the patients in order to improve patients with HF and DM adherence to the therapy and their self-care management was developed and used in this study, as it seems vital for them to become active self-managers and to be able to control their chronic condition.

1.2 Terminology

Quality of life: A working group for quality of life (QoL) by WHO in 1998 referred QoL as the patients' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" (WHO QoL Group., 1998). As there was not a global acceptable definition for QoL, scientists turned in a more practical approach to describe aspects of QoL. QoL is a measure of an individual's ability to function physically, emotionally and socially within his/her environment at a level consistent with his/her own expectations (Pais-Ribeiro, 2003).

Health related quality of life: Schipper et al. (1996) defined health-related quality of life (HR-QoL) as the functional effect of a medical condition and/or its consequent therapy upon a patient. HR-QoL can be defined as the value assigned to the duration of life as modified by the social opportunities, perceptions, functional states, and impairments that are influenced by disease, injuries, treatments, or policy (Patric et al. 1988, Ebrahim et al. 2005).

Self-management: Self-management is the ability of the patient to deal with all that a chronic illness entails, including symptoms, treatment, physical and social consequences, and lifestyle changes (Barlow et al., 2002). The factors that influence the development of expertise in self-care management are knowledge and skills about HF and DM, experience on self-care across common conditions and compatibility of the behavior (Dickson et al., 2011). Co- morbidities makes HF self-care more complicated creating barriers to HF self-care management such as the need for disease management knowledge, different instructions from multiple providers related to HF and DM, functional status limitations related to symptoms and psychosocial factors such as attitudes, lack of motivation, self-efficacy, anxiety and depression.

Self-efficacy: Self-efficacy is defined as a person's belief (confidence) in his or her ability to perform a set of actions; the stronger these beliefs of a person exist, the more likely he or she will initiate and continue activities that aid the attainment of a positive outcome (Bandura 1977, Mo and Coulson 2010).

Self-efficacy for managing chronic disease: Self-efficacy for managing chronic disease refers to "a patient's confidence in their management of different aspects of chronic diseases, such as symptom control, role function, emotional functioning and communicating with physicians" (Lorig et al. 2001, Fan and Lv 2014).

Motivational interviewing: Motivational interviewing is an evidence-supported collaborative, person-centred form of guidance to elicit and strengthen motivation for change (Rubak et al. 2005, Benzo et al. 2013). Motivational interviewing composer the transtheoretical model of behavior change by assessing a patient's ability to change a behavior and develops strategies to move toward taking action to change a behavior (Creper et al., 2015).

Diabetes mellitus: Diabetes mellitus is a chronic, metabolic disease characterized by elevated levels of blood glucose, which leads over time to serious damage to the heart, blood vessels, eyes, kidneys and nerves (Petersmann et al., 2019).

Diabetes mellitus type 1: Type 1 diabetes, once known as juvenile diabetes or insulin-dependent diabetes, is a chronic condition in which the pancreas produces little or no insulin by itself and this leads to the elevation of blood glucose (American Diabetes Association, 2021).

Diabetes mellitus type 2: Type 2 diabetes, usually in adults, occurs when the body becomes resistant to insulin or does not make enough insulin and this leads to the elevation of blood glucose (American Diabetes Association, 2021).

Glycosylated haemoglobin (HbA1c): HbA1c is as an indicator of the average blood glucose levels over the past 3 months and it is used as a diagnostic and screening tool for DM. Glucose molecules in the blood normally become stuck to hemoglobin molecules - this means the hemoglobin has become glycosylated. As a person's blood sugar becomes higher, more of the person's hemoglobin becomes glycosylated. The glucose remains attached to the hemoglobin for the life of the red blood cell, or about 2 to 3 months (American Diabetes Association., 2021).

Heart failure: It is a clinical syndrome characterized by typical signs and symptoms, caused by a structural and/or functional cardiac abnormality, resulting in a reduced cardiac output and/or elevated intracardiac pressures at rest or during stress (Ponikowski et al., 2016).

Ejection fraction: Ejection fraction is the percentage of the total amount of blood in the heart that is pumbed out with each heartbeat. A normal ejection fraction is 50% or higher (Ponikowski et al., 2016).

Heart failure with preserved ejection fraction: Heart Failure with preserved ejection fraction (HFpEF) is a clinical syndrome defined by a limitation in functional capacity due to shortness of breath and/or fatigue with signs of fluid retention secondary to elevated left ventricular (LV) filling pressures at rest or during exercise. This occurs due to impaired heart function and a left ventricular ejection fraction of ≥ 50% (Redfield, 2016).

Heart failure with reduced ejection fraction: Heart failure with reduced ejection fraction (HFrEF) is a complex clinical syndrome characterized by structural and/or functional impairment of the left ventricle, resulting in a decrease in heart pump function (left ventricular ejection fraction ≤ 40%) (Redfield, 2016).

Heart failure with mid-range ejection fraction: The heart's pumping ability is slightly below normal. Patients might not experience heart failure symptoms or they may have symptoms with physical activity but not at rest (Ponikowski et al., 2016).

Knowledge and the adaptation of knowledge as a health care behavior: Adequate knowledge is not the only predictor of effective self-care behavior; it involves the skills to interpret relevant information and use it to adopt the knowledge to health care behavior (Riegel et al., 2016).

Perceived social support: Perceived social support refers to how individuals perceive friends, family members/signifigant others as available, to provide functional and overall support when they need it. It is also related to better physical and mental health outcomes and HR-QoL (Ioannou et al., 2019).

Exercise tolerance: Exercise tolerance is the exercise capacity of an individual about his/her ability to make exercise and maintain the maximum workload achieved during the exercise period (Khan et al., 2020).

Anxiety and depression: Anxiety and depression are types of mood disorders. Depression causes feelings of sadness, hopelessness, and reduced energy. Anxiety has feelings of nervousness or worry and the two conditions can coexist (Taylor et al., 2017).

2. LITERATURE REVIEW

2.1 Epidemiology of Diabetes Mellitus and Heart Failure

Each disease of HF and DM independently increases the risk for the other as previously mentioned (Einarson et al. 2018, Gulsin et al. 2019). In cohorts' studies in both, HF with reduced ejection fraction (HFrEF) and HF with preserved ejection fraction (HFpEF), the prevalence of DM comes from 10% to 47% (Dei Cas et al. 2015, Sandesara et al. 2018). HFpEF is nowadays the most frequent type of HF, affecting more than three million adults in the United States only (Lindman, 2017). It is a heterogenous syndrome and one significant phenotype is found to be related with the underlying comorbid conditions like DM (Shah et al. 2016, Lindman 2017, Parikh et al. 2018). The 45% of patients with HFpEF are diabetics and the prevalence of comorbid DM is rising (Echouffo-Tcheugui et al., 2016). DM is also affiliated and with high risk of morbidity and mortality in HFrEF, patients and clinical trial data show that the negative prognostic association with DM is higher in patients with HFpEF than in HFrEF (De Groote et al. 2004, McDonald et al. 2008). In patients hospitalized with HF either HFrEF or HFpEF the prevalence of DM 2 is >40% and is even higher in patients with DM who are ≥60 years old (Boonman-de Winter et al 2009, Seferović et al, 2018).

Chronic diseases is the largest proportion of diseases and this will increase due to the ageing society putting pressure on the sustainability of the health care system (Randall & Neubeck 2016, Maresoca et al. 2019). The successful adaptation of the self-management of chronic diseases can keep the autonomy and the independence of the patients and can keep their social activities (Wildevuur & Simons 2015, Maresoca et al. 2019).

Since the prevalence of chronic HF increases as well as the ageing of the population all over the world, seems to be very difficult to maintain a certain quality of care for the chronic HF population (Lambrinou et al., 2012). Therefore, an affordable way to maintain and improve the quality of care for HF is to switch resources from crisis management (by hospitalizing patients) to health maintenance (through structured support) (Inglis et al. 2011, Lambrinou et al. 2012).

The Framingham Study was one of the first epidemiological stydies which found that there was a high risk for DM patients to develop HF (Kannel et al. 1974, Ho et al. 1993). In the EuroHeartFailure Survey, the prevalence of diabetes was similar in patients with HFrEF and HFpEF at 28% and 26%, respectively (Lenzen et al, 2004). In the CHARM-Preserved study, which included HF patients with ejection fraction (EF) > 40%, the rate of the DM was 28%, as well as and in the overall CHARM study population (MacDonald et al., 2008). However, HF with EF between 40-49% is now recognized as HF with mid-range EF (Lund et al., 2018). New studies show that patients with mid-range EF have more similar features to HFrEF than the HFpEF (Lund et al., 2018). In addition, in the I-Preserve study, which included HF patients with HFpEF, the 25% of the patients had diabetes (Kristensen et al., 2017). In I-Preserve study, DM was associated with high hazard of CV death or hospitalization and all-cause mortality (Kristensen et al., 2017).

Other clinical trials have also revealed similar associations between DM and HF. ALLHAT study showed that patients with diabetes had almost 2-fold risk for HF hospitalization or death (Davis et al, 2006). The association with diabetes was independent from that of coronary artery disease, equivalent in degree to that of coronary artery disease, and greater than that for electrocardiographic left ventricular hypertrophy and renal dysfunction (Davis et al, 2006). DM 2 was also associated with increased LV wall thicknesses and decreased LV internal diameter and these changes were associated with the increasing of the diabetes duration (Jorgensen et al, 2016).

There are more than 70,000 people with DM in Cyprus and over 20,000 patients with HF, where 3,000 new cases are diagnosed each year. More than 40% of people with HF have the commorbidity of DM (Radhoe et al., 2022). This coexistence of the two diseases worsens the clinical condition and worsens the HR-QoL of these individuals (Echoulfo –Tcheugui et al. 2016, Koshy et al. 2020). The fact that the incidence and prevalence of HF increases, the health care costs rise, creating further pressure to the Health Care System (Guha and McDonagh, 2013, Roth et al. 2015, Savarese and Lund 2017, Conrad et al. 2018, Cleland, Veldhuisen and Ponikowski, 2019, Lippi and Sanchis Gomar, 2020).

2.2 The Mechanisms Related to the Development of Heart Failure to Patients with Diabetes Mellitus

DM is related to HF development with three mechanisms: due to associated co morbidities, due to the development of coronary atherosclerosis or due to specific DMCM (Bauters et al. 2003, Jankauskas et al 2021).

The existence of related comorbidities or risk factors may account for the increased risk of HF in the patients with diabetes: e.g. dyslipidemia, hypertension, hypercoagulability, inflammation and obesity, are strongly related with the insulin resistance syndrome and are regulated by the nuclear peroxisome proliferator - activated receptors (PPARs). The activation of the PPAR-gamma, improves the sensitivity of insulin and the endothelial function, it lowers blood pressure and decreases inflammation (Martens et al, 2002). In the Framingham cohort study, diabetics, both men and women, were more obese than non –diabetics and had higher blood pressures. Diabetic women also had higher levels of LDL (Low Density Lipoprotein) values and the HDL (High Density Lipoprotein) values were lower in diabetic patients for both genders (Kannel and McGee, 1979).

Diabetic patients are at higher risk to develop atherosclerosis and this may contribute to the increased risk of HF. Elevated glucose level is involved in the pathogenesis of atherosclerosis at almost every step of the atherogenic process (Poznyak et al., 2020). Coronary artery disease (CAD) is the primary risk factor for HF development and the etiological factor in more than 50% of HF patients in North America and Europe (Pagliaro et al. 2020). Chronic inflammation is considered as one of the key factors in atherosclerosis development from the earliest stages of the pathology initiation and is one of the possible links between atherosclerosis and DM (Poznyak et al., 2020).

DM may predispose to HF development through the existence of the DMCM (Kenny & Abel 2019). The mechanism with which DM may independently induce HF from epicardial CAD is unknown, but there are several hypotheses, like the microangiopathy, the metabolic factors and the fibrosis (Yarom et al, 1992, Kenny & Abel 2019, Jankauskas et al 2021). Metabolic factors also seem to have an important role in the development of myocardial dysfunction since hyperglycemia, and increased turnover of free fatty acids may contribute to DM related myocardial dysfunction (Lopaschuk, 1996, Jankauskas et al 2021).

2.3 The Correlation of Heart Failure with Diabetes Mellitus Type 2

The most common causes of HF include the ischemic heart disease, atrial fibrillation, dilated cardiomyopathes and hypertension and some evidence propose that DM2 promote DMCM (Jia et al. 2016, Kenny & Abel 2019). In DMCM, there is an abnormal heart structure due to metabolic factors asoociated with DM as was mentioned before and not due to risk factors such as hypertension and CAD (Stanton et al., 2021). The DMCM is described in both types of DM (DM1 and DM2), but the early descriptions of DMCM does not specify the type of diabetes and are referred mostly to the factor that the duration and the increased glycaemia leads to high risk to develop DMCM in both types of DM (Jia et al., 2016). DMCM is usually asymptomatic and represents a kind of stage B HF (DMCM but without symptoms of HF) which is often underrecognized (Stanton et al., 2021). This process may progress to symptomatic HF (Boudina et al. 2007, Stanton et al. 2021).

The pathophysiologic connection between DM and HF refers to the glucose and the lipid metabolism that exist in DM2 which leads to the increasing of the oxidative stress, cellurar and endothelial damage, inflammation, fibrosis, mitochondrial dysfynction, and to systolic and diastolic dysfaction through various pathways (Teodoro et al., 2018). Diastolic dysfaction found in 40-60% in DMCM and insulin reristance with hyperinsulinemia is the most important prognostic factor in HF and not hyperglycaemia. Insulin resistance creates a fatty acid layer of oxidation phenotype of heart in DM2 patients and leads to the accretion of toxic lipids (Boudina et al., 2007). Hyperglycaemia also leads to oxidative stress by the activation of various pathways, of non-oxidative glucose metabolism, which leads to mitochondrial damage and to damage of the heart protein contractility, disfaction in the calcium handling and changes in genes expression (Brahma et al. 2017). In addition, hyperglycaemia activates the Renin-angiotensin-aldosterone system, inceses angiotensin II, increases cardiac fibroblasts and at the same time, icreases insulin resistance, hypertension and hyperlipidemia (Borghetti et al., 2018).

2.4 The Correlation of Heart Failure in Diabetes Mellitus patients with Glycosylated Hemoglobin Levels

UK Prospective Diabetes Study (UKPDS), the Diabetes Control and Complications Trial (DCCT) and the Stockholm Diabetes Intervention Study demonstrated that the incidence of HF in DM patients correlated with increase levels of glycosylated hemoglobin (HbA1c) (Buse et al., 2007). In observational studies of patients with diabetes, a higher HbA1c level was associated with a significantly increased incidence of HF (Erqou et al., 2013). Good glucose control (HbA1c=7.1%) led to the lowest risk of death in HF-DM patients and a higher HbA1c led to increase incidence of HF (Bertoni et al., 2004). Lind et al (2011) found that 1% increase of HbA1c increases to 30% the risk of HF in DM1 and Stratton et al. (2000) support that there is an increase of 8% for DM2 patients to develop HF. While DM2 occurs in approximately to 90% of diabetic patients this is a major and worrying issue (Stratton et al, 2000).

Registry data, give better estimation of the prevalence of the increased mortality and complications rate in HF patients with DM. The SOLVD study registry classed 23% (1,425) of the total 6,076 patients with left ventricular systolic dysfunction suffer from DM (Das et al, 2004). Other registry data have also shown a similar prevalence of DM in HF, of approximately 20-25% (Baliga and Sapsford, 2009). The EPICAL registry, study patients hospitalized for advanced chronic HF due to left ventricular systolic dysfunction - EF ‹30%, has shown that 26% of patients, had a history of DM, either type 1 or 2. Echouffo-Tcheugui et al. (2022) support that higher levels of fasting blood glucose and HbA1c is associated with higher risks of HF. Schaan et al (2017) support that when patients increase adherence to pharmacotherapy by 10%, the HbA1c levels is decreased by 0.1%.

Bauters et al (2003), refer that although the glucose control may be an independent risk factor for developing HF in diabetic patients, it is conceivable that these data concern a longer duration of DM and the development of HF may be related to the duration of diabetes, than to glycemic control. Many clinical trials found that an intensive glucose lowering therapy doesn’t lead to greater clinical outcomes in DM patients (Patel et al 2008, Duckworth et al. 2009). However, the scientific attention nowadays is remarkably increased due to recent trials of antidiabetic drugs for DM2 that lead to better clinical outcomes and have significant cardiovascular benefit (Marso et al. 2016, Rizzo et al. 2021).

2.5 Anti-hyperglycaemic Drugs and Risk of Heart Failure

Sulfonylureas are one of the older class of oral anti-hyperglycaemic drugs and in various studies were found to increase the HF risk (Mehta et al., 2020). A study in the UK studied DM2 patients and found that the use of sulfonylureas has 18% increased risk in developing HF compared with patients receiving metformin (Tzoulaki et al., 2009). A same increase in the admissions for HF was found in two other studies in patients using sulfonylureas compared with metformin (Gilbert et al., 2015). So, sulfonylureas are not recommended in HF patients especially due to the reliance on observational studies and due to the lack of RCTs (Dunlay et al., 2019). Thiazolidinediones (TZDs) are the anti-hyperglycaemic drugs that in trials showed increase in hospital admissions for NYHA class III and IV HF patients, due to the fluid retention from the activation of sodium channels in the collecting ducts (Dunlay et al., 2019). Metformin was contraindicated for patiens with HF due to concerns about lactic acidosis. However, observational studies and meta-analysis have shown that there is no increase in lactic acidosis unkike other therapies (Eurich et al., 2005). The metformin was associated with 20% risk reduction in all-cause mortality compared with other therapies (Dunlay et al., 2019). Metformin is nowadays one of the most popular drugs with both DM2 and HF (Dunlay et al., 2019). Insulin have positive effects on myocardial tissue and can improve haemodynamic measures but it can also cause weight gain, sodium retention, and edema which can increases the severity of HF (Dunlay et al., 2019). The ORIGIN trial, found insulin had a neutral effect on the outcomes including death from CV causes/hospitalization for HF, but not all the patients in the study were diabetics (Gerstein et al., 2012). Only one RCT evaluated the effect of insulin in DM patients and HF (Nielsen et al., 2016). The study found that there is no any impairment on cardiac function and no patients during the study were hospitalized for HF (Nielsen et al., 2016). The existing data are still not sufficient to blame insulin from causing any aggravation of the symptoms for HF patients. So in case a HF-DM patient had to start insulin, it is important to check daily signs and symptoms of fluid retention (Dunlay et al., 2019).

Three new classes of anti-hyperglycaemic drugs have an attention the recent years for the treatment of HF; the dipeptidyl peptidase-4 (DPP- 4) inhibitors, the peptide-1 receptor agonists (GLP-1RAs) and the sodium-glucose cotransporter-2 inhibitors (SGLT-2i) (Mehta et al., 2020). DPP4 inhibitors target on the incretin system and can block the degradation of GLP-1 with inhibiting the DPP-4 enzyme (Mehta et al. 2020). However, DPP-4 trials have shown that the medication have not any benefits in HF patients and may increase the risk of hospitalization, so they are recommended with caution in patients that are risk for HF (Stanton et al., 2021). The GLP-1RAs and the SGLT-2i, have shown very important CV benefit with glycemic control with no high episodes of hypoglycemia (Dawwas et al. 2019, Rizzo et al.2021, Maranta et al. 2021). The GLP-1RAs and SGLT-2i reduced non-fatal events of stroke and myocardial infarction and the CV mortality in patients with DM2 (Dawwas et al. 2019, Rizzo et al.2021). The clinical trial DAPA-HF (Dapagliflozin and Prevention of Adverse Outcomes in Heart Failure) in which were enrolled 4744 patients with HF and reduced EF were receiving excellent guideline-directed treatment before the addition of dapagliflozin (a SGLT2 inhibitor) or placebo. The DAPA-HF trial clearly showed that dapagliflozin was superior to placebo at preventing CV deaths and HF events (Kaplinsky, 2020). The SGLT-2i also improved the prognosis of HF patients and the use of GLP-1RAs found benefit on patients when the SGLT-2i was contraindicated (Cappetta et al. 2021, Giugliano et al. 2021, Lu et al. 2021). The HF-DM patients is a group of patients that not only most of them are older people, but they have difficulties to cope and manage the two conditions and are the patients that are exposed more in various infectious diseases (Banerjee et al.,2021). Patients with DM and CV diseases from the recent experience of the pandemic COVID-19 are more exposed to severe complications of COVID-19 and mortality, therefore, the best management of HF and DM is fundamental (Al Mahmeed et al. 2021, Banerjee et al.2021, Popovic et al.2021).

2.6 Digital Health Technology, Heart Failure and Diabetes Mellitus

Nowadays the use of digital health technology (DHT) for the management of chronic conditions is rising (Kallas et al., 2022). Digital health is defined as the use of communication and information technologies to treat/manage patients, educate HPs, do research or to improve/enable health and healthcare delivery (Pagliari et al., 2005). DHT includes e learning, telemonitoring, telerehabilitation, structured telephone support, m-health apps (Frederix et al., 2017). E learning is the information that is supplied to patients using web-based educational material (Frederix et al., 2017). Telemonitoring includes the provision of data via telephone lines, satellite or wireless networks (Frederix et al., 2017).

Structured telephone support is the monitoring and the delivering of self-care management through classic telephone technology (Inglis et al., 2011). Telerehabilitation refers to the rehabilitation from a distance by using devices for delivering the information to the patients / caregivers e.g coaching from a distance via email/SMS/telephone, social interaction, e-learning etc (Frederix et al., 2015). m-Health apps or mobile applications, are software on a smartphone /on a tablet which can be used as a tool for providing services for cardiac patients (Neubeck et al., 2017).

Mostly the use of DHT has been used during the COVID-19 pandemic, which enabled HPs to deliver care through mobile applications, text messaging platforms, telehealth etc to manage patients with chronic diseases (Qiu et al., 2021). Most platforms of DHT are focused on managing a single disease and not comorbidities (Doyle et al., 2021). The Medly program is a program that used a mobile phone to record daily HF readings and receive personalized self-care messages generated by an algorithm (Ware et al., 2020). This program reduced health service utilization and improved clinical, HR-QoL and patient self-care outcomes (Ware et al., 2020). A meta-analysis found that telemonitoring programs were found to be associated with reduced mortality and lower rates of HF-related hospitalizations (Klersy et al., 2009). Therefore, the effectiveness of the DHT in patients with the two deseases (HF-DM) is yet unknown. There was one study that assess if a structured telephone support could improve HR-QoL and reduce HbA1c for DM2 patients and heart disease, but the study had no any benefit and did not improve HR-QoL. Nevertheless, is important the DHT to be used in HF patients with DM for the better investigation of HR-QoL, health behavior, medication adherence and other factors associated with various aspects related to this group of patients. However, before using the DHT some bariers should be considered like the lack of access, financial issues, device failure, specific group needs (elderly, culturally/ linguistically issues) and training of HPs in using DHT (Frederix et al,. 2015).

3. HEART FAILURE AND DIABETES MELLITUS MANAGEMENT PROGRAMS

Many HF management strategies have been developed over the years with the aim to prolong the lives of patients with HF (Yancy et al. 2018, McDonagh et al. 2021). These strategies focused on improving symptoms, functional capacity, patient HR-QoL, and reducing the risk of HF hospitalizations. The last 30 years has been an increase in improvement in the pharmacological and in cardiac surgery therapies to help improve the clinical symptoms for HF patients (Riley & Beattie 2017, McDonagh et al. 2021).

However, delivering the best treatment plan in HF care is complex because multiple medications, cardiac devices and lifestyle adaptions, are unique to each patient based on their diagnosis, needs and symptoms (Yancy et al. 2018, McDonagh et al. 2021). In HF patients with comorbidities like DM, make the treatment plan more complex (Yancy et al., 2018). Re-hospitalizations for these patients have not been improved even though there are many successful management programs, and more research is needed to find out what are the essentials that make such a program successful in long term (Kyriakou et al., 2019). Therefore, it is very important a holistic approach in providing HF and DM care that includes a team of professionals, consisted of HF cardiologists and specialist HF and DM nurses that can provide individualized patient care (Yancy et al. 2018, McDonagh et al. 2021).

A comorbidity like DM complicates HF self-care management and makes adherence to the therapy more unlikely (Lambrinou et al. 2014, Lambrinou et al. 2018). These patients have more rehospitalization rates due to complex problems such as fluid overload and insufficient glucose control but with better self-care management, this could be avoided (Riegel et al., 2021). Therefore, it seems that current management programs are not effective enough on HF and DM patients, especially nowadays that the Health Care Systems have to deal with many challenges like pandemic and financial constraints (Riegel et al., 2021). The National Health Care System (NHS) - a successful and productive Health Care System in the United Kingdom the previous decades - now is threatened with destruction with enormous pressure, rising waiting times, workforce shortages and patients fighting to access the care they need (Dayan et al. 2021, Wilson et al. 2023). As a result, the satisfaction and the quality of the care provided is significantly reduced. This is due to a mixture of factors including a growing and ageing population that needs care, the lack of social care support, pandemics (e.g.COVID-19) and medical services with more demands (Dayan et al. 2021, Wilson et al. 2023). HF when exists with DM requires a complex self-care recommended therapy and novel medications like SGLT-2i and GLP-1RAs as was mentioned previously (Lambrinou et al 2018, Cappetta et al. 2021, Giugliano et al. 2021, Lu et al. 2021). Currently, 32-51% of the hospitalized patients with COVID-19 was sufferring from DM and CVD and the new medications have shown a beneficial action on the outcomes of COVID-19 (Banerjee et al.2021, Popovic et al.2021). Therefore, it is of significant importance for patients with HF and DM to manage their health status the best possible way and adhere to the recommended therapy (Cha et al. 2020, Huang et al. 2020). There is also a great need to find an effective way to support the older people with chronic diseases and comorbidities like HF and DM.

3.1 Motivational Interviewing

In recent years, MI approach has been applied to several chronic illnesses or problematic behaviors patients with other problem behaviors promoting behavior change like in alcohol drinkers (Miller 1983, Brodie et al. 2008). It is found to enhance individual commitment to change (Rubak et al, 2013).

Paradis et al. (2010) bases the MI on four principles: 1. The nurse should express empathy 2. Iintroduce doubt in the mind of the patient about a behavior that must be changed and the consequences of that behavior 3.‘Roll with’the resistance of the patient and 4. Reinforce the self-efficacy of the patient. The nurse may guide the patients to find their strengths and solutions and not proposing ready-made answers. The MI can emphasize the humanistic issue and person-centred approach that people are normally motivated for growth and self-direction (Riegel et al. 2009, Letourneau et al. 2014, Carr 2017).

3.2 Patient - Centred approach of Chronic Diseases and Self-management

Patient-centred approach is found to be effective in changing the patient’s behavior. Patient-centred care respects and responses to individual patient’s preferences, needs, and values and ensures that, patient’s values are able to guide the clinical decisions (Committee on Quality of Health Care in America, 2001). It highlights the importance of knowing who is the person behind each patient, a patient as human being, who has feelings, needs and will, in order to engage the person as an active partner in his/her own treatment and care (Ekman et al. 2011, Soderlund 2018).

The educational interventions, which involve patients’ collaboration, seem to be more effective that the didactic ones in improving glycemic control, lipids and the weight of the patients. Evidence shows that the involvement of the patients according to their individual needs, supports the effectiveness of self-management training, in chronic diseases (Norris et al, 2001). For HF-DM patients, self- management support is found to be vital (Reilly et al 2009, Giamouzis et al 2010). Lots of evidence have shown that knowledge, self-efficacy and the provider of support are correlated with good self-management outcomes (Williams et al 1998, Riegel and Carlson 2002, Koelling et al 2005, Soderlund 2018).

Self-care management is a cognitive and behavioral process which refers to regular maintenance tasks like being adherent to medications, engaging in physical activity, proper diet, monitoring weight gain and management of the symptoms (Riegel et al. 2000, Jessup et al. 2003). Demands of self-care are increased when patients have HF and DM, simultaneously. The self-care regimens are often overlapped and conflicted because an exacerbation of one condition may trigger the other condition to become out of control. Patients need support to improve their knowledge, skills and confidence in order to be able to manage these demanding comorbidities; otherwise, they may experience greater symptoms (Bodenheimer et al. 2002, Ha et al. 2016, Chan et al. 2017).

4. SUPPORTIVE CARE IN HEART FAILURE

The concept of supportive care originates in cancer. Nowadays, supportive care applies in all chronic life- threatening diseases including HF (Ahmedazai et al. 2000, Beattie & Goodlin 2008). The Sheffield model which is a multidisciplinary supportive care model firstly introduced for cancer patients, (Ahmedzai et al., 2000) is a model that can be implement for patients with HF (Beattie & Goodlin., 2008). Based on this model, health care providers have to follow the trajectory of each patient and integrate supportive care based on the needs in each time point. (Beattie & Goodlin., 2008). Thus, health care providers avoid to 'change' supportive care to palliative care; they provide patient with comprehensive heart failure care (Goodlin et al. 2004, Beattie & Goodlin 2008). Comprehensive HF care is consisting by the following four aspects: communication, education, psychological and spiritual issues and symptom management (Goodlin et al., 2009).

Supportive care changes, according to the patient's needs. HF disease management and supportive care should not be applied sequentially; rather, both types of care should be offered concurrently, integrated in proportions that incorporate the course of the individual's illness and patient's preferences (Goodlin et al., 2004). The amount of supportive care required by the patient may increase as function worsens (Goodlin et al. 2004, Siouta et al. 2016). A "patient-centred, family-focused" structure should frame the approach to care for advanced HF in light of the symptoms and burdens occurring throughout the illness (Goodlin et al., 2004). Supportive care addressing physical, psychosocial, or existential distress and strategies to manage and cope with HF should be provided concurrently with evidence-based disease-modifying interventions in comprehensive HF care (McDonagh et al., 2011).

4.1 Supportive care through continuing communication

Continuing communication with the patients through structured telephone support can help with monitoring, self- care management, or both (Bui & Fonarow 2012, Black et al. 2014). Patient seems to have better follow up if health care professionals use ' reminder messages ', either via telephone calls or SMS (short message service), so they can reinforce the ability of the patients to maintain self-care behaviors (Bui & Fonarow, 2012).

MI may also be provided through telephone intervention and in many studies, this was proved to be efficient in performing self-care management (Perry & Bennett 2006, Kreman et al. 2006, Riegel et al. 2006, Hanlon et al. 2017). In the area of diabetes management, the use of mobile phones for disease management has been well documented (Blake 2008, Skinner & Finkelstein 2008, Wang et al. 2020). This kind of interventions in combination with health behavior theories and sciences are promising on improving outcomes (Hedtke, 2008). Dennis et al. (2013) and Sun et al. (2019) showed that planned (i.e. weekly or monthly) telephone calls to support the patients with chronic diseases are most effective in improving self-management skills, especially in patients coming from vulnerable groups, like the older people. These regular contacts can help patients to develop their self-management skills over time, whereas the unscripted aspect allowed the coach to tailor support to the individual needs of each patient. The calls aiming to provide support and encouragement to patients, promote healthy behaviors like treatment control, proper diet, physical activity and mobility (Hutchison & Breckon 2011, Sun et al. 2019). In order to develop a patient - centred program, it is important to know what are patients' needs based on their perspectives through qualitative studies that patients express their own feelings, despite the fact that exist promising management programs that improve HF related outcomes like readmission rate (Garin et al. 2009, Lambrinou et al. 2013).

5. SYSTEMATIC REVIEWS

5.1 A qualitative meta-synthesis of patients with heart failure perceived needs

In order to summarise the perceived needs of patients with HF a systematic review and a metasynthesis were established. The main issue that brought out was what HF patients describe as major needs and which intervention was effective for them. The systematic review consisted from qualitative studies including adults with HF who interviewed about their supportive needs.

5.1.1 Introduction

The HR-QoL of patients with HF is affected by the various changes they experience on the issues that affect their physical, emotional, cognitive, social, economic and spiritual level. Graven & Grant (2014) found that all the patients living with HF have different experiences that is unpredictable in personal level, but at the same time, there are common factors following this experience. The qualitative studies of Aguado et al. (2010), Schulz et al. (2010) and Wang et al. (2015) have already explored patients with HF needs, but the results of a qualitative meta-synthesis can help HPs to develop interventions based on patient's true needs and different experiences that are not yet being dealt with. The aim of the review and meta-synthesis was to identify the needs of HF patients as they describe these needs themselves.

5.1.2 Methods

Two researchers established a literature search in electronic data basis PubMed, CINAHL, PsycoINFO, and EBSCO. Inclusion criteria were used were: articles that use qualitative methodology involving patients with HF, and have explored patient needs from a patient perspective, articles were published in the english language and articles involving carers/caregivers were included only where the patient results were presented separately. Exclusion criteria were defined as articles including populations other than patients with HF or articles not presenting results for patients with HF separately, articles focusing on the patients' experience or perspectives generally related to HF but not related to their needs, and studies exploring caregivers and/or family needs. The search yielded 518 articles from which 29 duplicates removed, a further 447 papers were excluded after the titles and abstracts of the articles had been reviewed. The remaining 42 articles were assessed for full eligibility, and 11 publications were found to fulfill the inclusion criteria and were therefore included in the systematic review and meta-analysis.

The methodological quality of the included articles was assessed using the Consolidated criteria for reporting qualitative studies (COREQ) item checklist. This was conducted in order to gain an overview of the methodological quality of the studies included. No study was rejected due to low methodological quality. The checklist consists of 32 specific items for reporting qualitative studies and includes generic criteria that are applicable to all types of research reports. The criteria included support researchers to report upon important aspects of the research team, study methods, context of the study, findings, analysis and interpretations.

In order to verify the validity of the interpretation within the texts, a ‘thematic synthesis’ methodology was used in meta-synthesis. This method consists of a three-step process: 1. Free line by line coding of the findings of the primary studies, 2. Free codes extracted and then organized into related areas to build descriptive themes and 3. Analytical themes were developed. After this process, researchers went beyond the systematic synthesis of primary studies and interpreted the findings-results in a critical way. New themes were produced to combine similar needs that appeared for the meta-synthesis. The final themes were: continuing person-center care, social support, supportive care, palliative care and self-care management. Researchers’discussions also disclosed the need for continuing support of the patients in order to be able to cope with the needs raising through the HF trajectory. The core theme then raised and researchers developed the core theme: ‘Wind beneath my wings’ (Figure 1). A description of the core theme and each of the main themes is referred below.

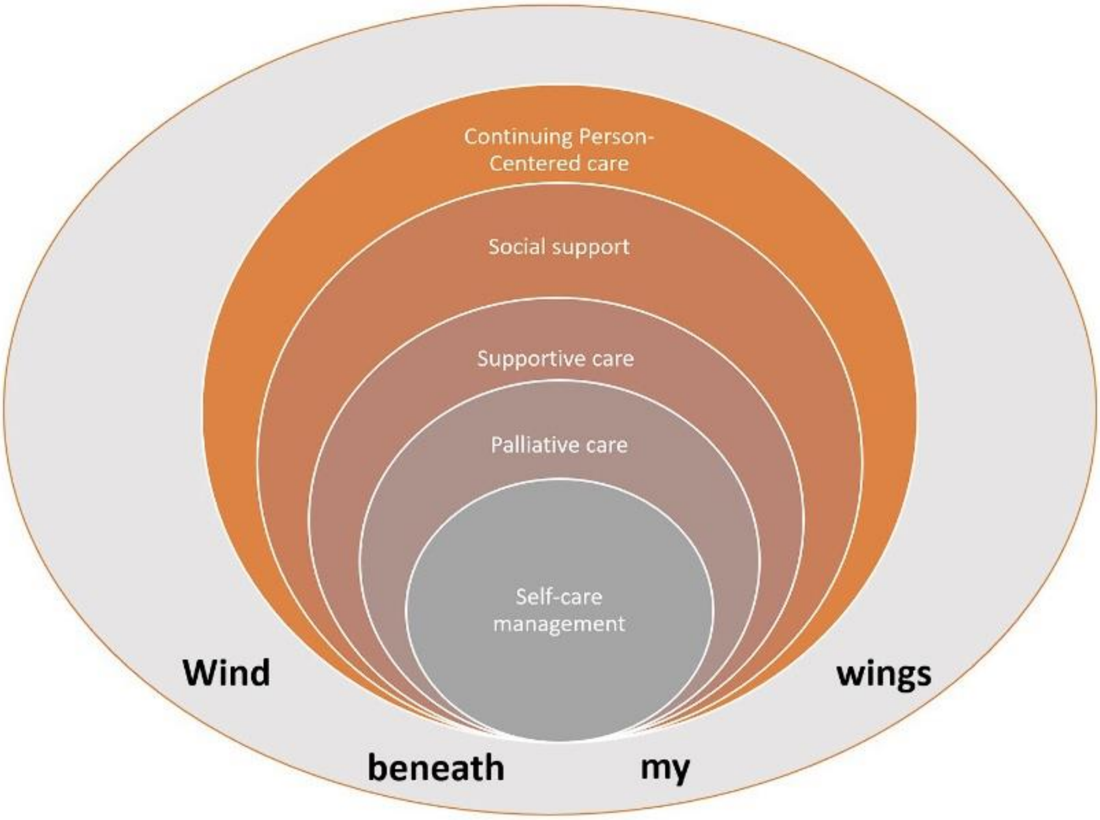

Figure 1: Final themes covering all topics related to patients with heart failure needs

5.1.3 Results

From the systematic review, eleven studies were assessed as eligible and were included in the review and meta-synthesis. Through the three-step process of the thematic synthesis one core theme (namely ‘Wind beneath my wings’), and five main themes revealed: continuing person-centred care, social support, supportive care, palliative care and self-care management. A description and relevance of the core theme, and each of the main themes, is listed below.

5.1.3.1 Core theme: *Wind beneath my wings*

Researchers recognised the mechanism to meet the needs extracted from the literature review and the meta-synthesis and revealed the core theme: ‘Wind beneath my wings’. Five different categories also revealed from the results to cover patents’ needs, interacting with each other: self-care management, palliative care, supportive care, social support and continuing person-centred care (CPCC).

“[…] I would like to know, what the problem is. I would like to know, what treatment I need which one I should emphasize”. All themes are correlated between each other as shown in Fig. 1, starting from the self-care management and ending up with a continuing process, with the patient in the centre.

5.1.3.2 Main themes

5.1.3.2.1 Self-care management

Selfcare is the basis of HF management. Self-care includes adherence to behaviors, such as maintaining medication menu, a low sodium diet, symptom monitoring (self-care maintenance) to maintain physiological stability and response to symptoms when they happen (self-care management) (Dickson et al., 2011).

“[…] How to protect myself and avoid risk factors […] As long as I have ways to obtain the information, I hope I can get as much information as I can”

5.1.3.2.2 Palliative care

Palliative care for HF patients according to Hupsey (2012) and Allen et al. (2012) has the double feature of treating symptoms and ensuring that the treatment plans of the patients, match their goals. Palliative care provides care in the relief of pain and other troublesome situations and offers a support system to help patients live as actively as possible until they die (WHO 2009).

“This made me feel sick, uncomfortable. If you see what …Is this your last hour? […]”

5.1.3.2.3 Supportive care

Goodlin et al. (2004) claims that Supportive care is “the care that helps the person and people important to them to cope with life-limiting illness and its treatment – from before diagnosis, through diagnosis and treatment, to cure or continuing illness, or death and bereavement”

Supportive care in HF patients is fundamental because can manage different aspects for the patients like both physical and psychosocial issues but also various comorbidities and the improvement of the QoL for patients and their families is almost certain (Hupsey, 2012). Supportive care plays an important role in positive change of patient's needs and leads to more positive HR-QoL as defined by patients and their families especially in difficult situations like post discharge period (Chung et al., 2011).

"[…] it's good when you have someone who looks after you […] I do not want too much care […] too much responsibility"

5.1.3.2.4 Social support

Hunt et al. (2012) state that social support is a condition with a variety of concepts, which positively affects the outcomes of patients in multiple chronic illnesses, including HF.

"I don't meet people […] very very lonely. Very very lonely"

"I am worried I do not have someone to live with. I live here alone no one even to make me a cup of tea"

The emotional support, instrumental/tangible support, informational support and appraisal support (Zhang et al., 2015) are the four kinds of social support that can influence disease-related outcomes in patients with HF (Zhang et al., 2015). There is also the informal and formal social support where the informal refers to the support from the family members, friends and neighbors and the formal to the support from health professionals (HPs) (Shiba et al., 2016).

5.1.3.2.5 Continuing person-centred care

Ekman et al. (2017) support that CPCC is the key that give solution to an effective management of a disease. It is an efficient way to give to the patient the way to collaborate with the HPs and to encourage the empowerment of the patient so they can take part in finding solutions to their problems.

"No, no, nothing about that at all. Just this great stream of medicines, between puffs and pills."

"I suppose they do (explain symptoms) but it hasn't penetrated."

"What they explain (to) me, I forget."

"[…] But who is going to explain it to me so that I understand? I haven't met anyone yet who can do that "

All themes are interacted between them. As it starts from the self-care management, it ends to the continuing process and the patient is in the center (Figure 1).

5.1.4 Discussion

The results of the current meta-synthesis could be analyzed and be explained in two ways: the first way follows the role of the patient to become active self-manager able to control his chronic condition while the other way refers that all actions of all the mechanisms of disease control reach the person with HF and his unique needs. Each person is unique and has a different perception of his/her life, even when experiencing similar situations of uncertainty and restriction with others (Alharbi et al., 2012). Thus, the key solution remains person-centred care. Ekman et al. (2011) refers to giving the person the opportunity to present her/himself as a person in the form of an illness narrative as a starting point for building a collaborative, egalitarian provider (care and treatment expert)-patient (person expert) partnership that encourages and empowers persons to actively take part in finding solutions to their problems. “Wind beneath my wings” is the role of the HPs (the wind), who encourage patients (the wings) to take part in their care, to control and take decisions for their own health and HR-QoL. Patient empowerment helps increase patient awareness as well as encouraging mutual trust and open communication between patients and HPs.

It is important that HPs place the patient with HF at the centre of every care effort and help him/her to address his/her unmet needs to achieve the best possible HR-QoL. (Ekman et al., 2017). Kane et al. (2015) refer to CPCC as the answer to the management challenges for HF, by incorporating patient preferences, values, beliefs, illness understanding, illness experience and information needs. However, is this enough to address the unmet needs of HF patients? The answer is CPCC in the context of supportive care. Supportive care could be developed and provided starting from the perspective of CPCC from the stage of diagnosis until the end of life. The concept of CPCC integrates patient and family preferences and needs into the goals of care, manages symptoms to the level of comfort desired, and attempts to reduce the burden of illness (Nguyen et al., 2019). But before providing supportive care, it is necessary for HPs to assess patient’s needs and develop a process that regularly monitors patients’ needs, since HPs should extrapolate the unmet needs of each patient with HF via ongoing processes because the needs can rapidly change depending on the trajectory of the illness (Ekman et al., 2017). Even though a lot of successful management programs and therapies have been developed for HF patients, evidence show that people with HF frequently lack HR-QoL (Jonkman et al., 2016) and do not always, feel that HPs respond to their needs (Jonkman et al. 2016, Ekman et al. 2017). Supportive care that is a continues process may change the perception of care through the HF trajectory. The meta-synthesis proves the need for a CPCC model in patients with HF that focuses on the ongoing needs of the individual and it is flexible as the needs change according to various factors affecting the patients.

The relevant article of the systematic review and meta-synthesis has been published and presented in Appendix I.

5.2 Factors associated with adherence to therapy for heart failure patients with diabetes mellitus

In order to identify the factors influencing adherence to the therapy of patients with HF and DM a systematic review was established (Philippou et al., under review). Previous studies showed only 50% of persons suffering from chronic diseases adhere to the recommended therapy (Rybacki et al. 2002, Van der Heide et al. 2015).

5.2.1 Introduction

Adherence to the therapy refers not only to the proper behavior on taking medications, but also to the patient following a proper diet, exercise and lifestyle changes (Dunbar et al., 2015). HF when exists with DM requires a complex self-care recommended therapy (Krumholz et al 2006, Ekundayo et al. 2009, Lambrinou et al. 2018,). So, is of significant importance for patients with HF and DM to manage their health status the best possible way and adhere to the recommended therapy (Chen et al. 2020, Huang et al. 2020). Even though self-care management strategies are the key to reduce HF hospitalizations by educating patients on how to manage and monitor HF symptoms and their comorbid conditions at home, not many patients are found to have the opportunity for counselling and education (McDonagh et al., 2021). Patients' adherence and self-care management can be improved through health education and support (Lainscak et al. 2005, Rector et al.

2005, Riegel, et al. 2008, Lambrinou et al. 2011, Lambrinou et al. 2018). It seems that current management programs are not effective on patients with comorbidities such as HF and DM (Piette et al. 2005, Kerr et al. 2007).

5.2.2 Methods

Electronic data basis PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Cochrane Library were used to find studies for the particular topic. The key words used were 'adherence to therapy', 'heart failure', 'diabetes mellitus', 'comorbidity', in different combinations using the word 'AND'. The tool 'similar articles' of PubMed was also used.

Inclusion and exclusion criteria were predefined. Inclusion criteria were studies published in English language until the end of August 2023 evaluating factors influencing adherence to the therapy of patients with the comorbidity of HF and DM. Exclusion criteria were studies that included populations with other CVD than HF, such as hypertension or coronary artery disease (CAD), populations with other comorbidities than of HF and DM, unpublished studies, pilot studies and studies of which the population was children. At first, two of the authors separately searched the electronic basis, screened the titles of the articles found and selected the potentially appropriate ones. Then, the eligibility of the appropriate article abstracts was assessed by reading the abstract of reviewing relevant titles. The whole procedure included full consensus, after detailed assessment of full text documents and the input of a third author whenever a query was raised. Two authors assessed the methodological quality of the included studies. The studies were assessed using the Effective Public Health Practice Project (EPHPP) quality assessment tool for quantitative studies (EPHPP 1998, Thomas et al. 2004).

5.2.3 Results

5.2.3.1 Overview of The Studies

Current search yielded 987 articles. 929 articles excluded of not meeting the inclusion criteria, 58 full text articles retrieved and 23 review articles and 27 articles not referring to the comorbidity of HF & DM were excluded. Finally, eight articles were used for the current systematic review (Greenberg et al. 2007, Kerr et al. 2007, Ciccone et al. 2010, Edelmann et al. 2011, Kapoor et al.2011, Cha et al. 2012, Dunbar et al. 2015, Peres et al. 2019). From the eight studies included in the current systematic review, five originated from the USA (Greenberg et al. 2007, Cha et al. 2012, Kerr et al. 2007, Kapoor et al.2011, Dunbar et al. 2015) one study was established in Italy (Ciccone et al., 2010) one in Germany (Edelmann et al., 2011) and one in Brazil (Peres et al., 2019). All studies used quantitative methodological approach.

5.2.3.2 Methodological Quality Assessment

The eight studies were assessed to find the degree to which the selected quantitative studies follow the quality features of selection bias, study design, confounders, blinding, data collection methods, withdrawals and drop-outs, intervention integrity and analyses. The EPHPP quality assessment used for the Methodological Quality Assessment of the studies.

5.2.3.3 Adhererence, Health Care System and Therapy Related Factors

Patients with HF and DM were less likely to receive smoking cessation counseling (OR 0.89, 95% CI 0.81-0.98) and blood pressure control (OR 0.81, 95% CI 0.78-0.84) and to attain the all-or-none composite measure (OR 0.96, 95% CI 0.93-0.99) during their hospitalization (Kapoor et al. 2011). In addition, HPs found it difficult to apply measures in patients with HF, with or without DM and control their optimal blood pressure (Greenberg et al., 2007).

Patients with DM were more likely to receive an aldosterone antagonist for reduced left ventricular ejection fraction (OR 1.05, 95% CI 1.00-1.11), lipid-lowering agent (OR 1.33, 95% CI 1.26-1.41), and influenza vaccination (OR 1.05, 95% CI 1.01-1.09) (Kapoor et al., 2011). The percentage of HF patients with DM that received b-blocker therapy and angiotensin converting enzyme inhibitor/angiotensin receptor blocker (ACEi/ARB) at the 60-to 90–day follow up period was higher than that between HF patients without DM (Edelmann et al., 2011). Patients with HD and DM with preserved ejection fraction (HFpEF), were less likely to receive recommended medical regimen, ACEi or ARB or beta-blockers, compared with patients with reduced ejection fraction (HFrEF) and DM (Greenberg et al. 2007, Edelmann et al. 2011). They had also worse blood pressure control, compared with patients with HFrEF and DM, who received the above medical regimens.

5.2.3.4 Adherence, self-care management and Condition Related Factors

Patients with severe HF and DM were found to have lower self-care management scores, giving priority in managing their HF and showing DM self-management to have less priority and effectiveness (Kerr et al. 2007, Peres et al. 2019). Patients with severe HF (NYHA classes II-IV) and DM were found to need more support for self-care management activities and care priorities of their conditions (Kerr et al., 2007). In contrast, HF patients of NYHA classes I and II did not show differences on prioritization and self-care management of the two chronic diseases on physical activity and diet. HF as a comorbidity and severe and not mild HF were found to increase the difficulty for self-care management in patients with DM (Kerr et al., 2007). Patients with DM2 and HF are 2.3 times more likely not to follow the medication adherence (Peres et al., 2019). Patients with HF and DM were found to consume more saturated fat, protein, dietary fibers, lower carbohydrate and higher levels of sodium than HF patients without DM (Cha et al., 2019).

5.2.3.5 Adherence, self-care management and Patient Related Factors

HF and DM self-care intervention had effects on improving HRQoL (Dunbar et al., 2015). Patients with HF and DM in the intervention group improved HF total ($p=.002$) and physical ($p<.001$) HR-QoL scores at three months with improvement at six months and improve HR-QoL scores compared with control group at three months ($p=.04$). There was also improvement of the health status ratings ($p=.04$) at six months compared to baseline. The intervention group also improved the 6 Minute Walking Test (MWT) distance ($p=.03$) while control declined ($p=.01$). The intervention group increased self-reported physical activity between the baseline and the 6 months ($p=.01$).

The introduction of the empowerment models in the management of patients with HF and DM made patients to have more involvement in their self-care management, which increased their motivation to manage several of their problems raised (Ciccone et al., 2010). Self-monitoring behavior was found to be increased during the study period with an additional 20%-27% of patients in each condition taking a more active role on the management of their condition. In addition, patients were taking more action to adopt healthier eating habits, increase their physical activity and quit smoking $p = .01$) (Ciccone et al., 2010).

5.2.4 Discussion

The factors influencing adherence to the therapy found in eight studies (Greenberg et al. 2007, Kerr et al. 2007, Ciccone et al. 2010, Edelmann et al. 2011, Kapoor et al. 2011, Cha et al. 2012, Dunbar et al. 2015, Peres et al. 2019), can be divided to three categories:

a. Health Care System and Therapy Related Factors,

b. Condition Related Factors and

c. Patient Related Factors studies

5.2.4.1 Health Care System Related Factors and Therapy Related Factors

Health Care system related factors refer to the proper functioning of the health care system and is one of the factors influencing adherence to the therapy of patients with HF and comorbid DM. Empowerment models by the HPs in the Health Care System can assist patients to arrange their visits with the medical doctors and can give them the necessary support based on their level of care. A good patient-HPs relationship seems to improve adherence to the therapy and clinical parameters of patients with HF and DM who show better control of their conditions (Rose et al. 2000, Ciccone et al. 2010) so they can develop a 'partnership' between them with which the patients gradually manage to feel motivated and self-confident. A good relationship among patient-HPs can help the patients to improve their intensity of physical training, take more action, quit smoking and adopt healthier eating habits. These factors may develop the necessary feelings for behavior changes to better control their health status and their clinical indicators, such as low-density lipoprotein levels (LDL), body mass index (BMI) rating and blood pressure values (Mola et al. 2008, Ciccone et al. 2010). Such management programs may motivate patients to make behavior changes that can affect their health status. Through motivation, HPs guide patients to find their confidence, take action, and not just give ready-made answers (Lambrinou et al. 2019, Carpenter et al. 2019). MI emphasizes the humanistic perspective and person-centred approach when people are normally motivated for further and self-acting development (Riegel et al. 2009, Poudel et al. 2020). Person-centred care is the way to demonstrate how symptoms could be integrated into clinical practice (Ekman et al. 2018, Poudel et al. 2020, Ghizzardi et al. 2022).

The health care system and HPs must understand better the various needs of patients with HF and DM adapt health care strategies and provide services to balance both; the benefits and the risks of the medical recommendations, as well as patients' preferences (Rubin et al. 2005, Kerr et al. 2007, Kyriakou et al. 2021). The HPs must have specific knowledge and training on managing chronic comorbid diseases, such as HF with DM. Patients with HF and comorbid DM generally receive only little help by HPs in setting priorities about self-care management of their comorbid condition (Granata et al., 2008). The introduction of telemedicine or telemonitoring in the community, may give nurses a new decision-making tool in the immediate follow up of the chronic patients (Lamothe et al. 2013, Brahmbhatt et al. 2019).

Supportive programs by HPs that promote problem solving and develop coping skills, may develop effective behaviors in patients with HF and DM (Kyriakou et al., 2020) and increase their self-efficacy and access to social support (Lorig et al. 2006, Kerr et al. 2007, Kyriakou et al. 2021). Effective management of HF and DM was the most important factor during the COVID-19 pandemic since DM was found to be correlated with high mortality, showing how patients with DM are more vulnerable to infections or other diseases in general (Chen et al. 2020, Huang et al. 2020).

Therapy related factors is another important factor that influences the adherence to therapy in patients with HF and DM. The use of evidence-based therapies for patients with HF and DM must be used for better management of the disease (Greenberg et al., 2007) and to reduce the risk of mortality for HFrEF and HFpEF. In addition, guideline-recommended therapies are fundamental to be followed for HF and DM patients for better control and not only for patients with HFrEF (Edelmann et al., 2011). HF is a factor that is associated with non-adherence to the pharmacotherapy in DM2 patients and this can be improved through the screening for HF and the interventions (Peres et al., 2019). The medication adherence measures can be used as important tool or quality indicator that can improve the performance of health care providers and contribute to health care services improvement and effectiveness (Seabury et al. 2015, Aktaa et al. 2022).

5.2.4.2 Condition Related Factors

Condition-related factors are strong determinants of adherence and include the clinical conditions (physical, psychological, social and vocational), the type and the severity of the disease and the availability of effective therapies (Kerr et al., 2007). In addition, the impact of the condition related factors depends on how these factors influence patients' risk perception, the importance of adherence treatment, and the priority placed on adherence (WHO, 2013).

There is the necessity for HPs to inform patients with HF and DM, of the importance of setting priorities to their DM self-management and keep their HbA1c in normal levels, to avoid the hospitalizations (Cha et al. 2012, Dickson et al. 2013). Hyperglycemia can produce many and serious macrovascular complications such as CAD, peripheral arterial disease and stroke and /or microvascular complications such as diabetic neuropathy, diabetic nephropathy, and retinopathy (Dickson et al., 2013). These complications lead to the reduction of the HRQoL and to long-term hospitalizations for patients with DM (Dickson et al. 2013, Seferović et al. 2018).

5.2.4.3 Patient Related Factors

Patient related factors such as patients' knowledge and beliefs about their illness, motivation and confidence (self-efficacy) for self-care management and expectations on the outcomes of the therapy and the consequences of poor adherence, interact in ways not yet fully understood to influence adherence behavior (Ekundayo et al., 2009).

Patients with HF and DM decrease their prioritization for DM management due to the lack of knowledge and information about their illness and its complications. They also ignore how the poor adherence affect their outcomes including mortality and complications (Adams et al. 2005, Kerr et al. 2007). It is common for patients to underestimate the management of DM because DM usually does not cause acute events like those that HF does, such as dyspnea (Kerr et al., 2007); so, they pay more attention to the management of HF. This makes sense since being short of breath is felt, whereas a high sugar is not associated with severe symptoms. Therefore**,** a well-prepared HP team is crucial to achieve the best care and adherence to therapy for patients with HF and DM as indicated by the guidelines and clinical trials (McDonagh et al., 2021). Motivational multidisciplinary programs should be promoted, in order to achieve the proper adherence for these patients (Cha et al. 2012, Lambrinou et al. 2014). A motivational interview program using the stages of change may increase patients' confidence and improve self-care management (Paradis et al., 2010); patients may be motivated for lifestyle modification e.g. healthy diet and exercise (Ciccone et al., 2010).

The introduction of empowerment models in the management of patients with HF and DM seem to allow the patients the ' partnership' model with the HPs and this will help them to build their self-confidence and the motivation to make lifestyle modification, increase self-monitoring and become more adherence to treatment recommendations (Riegel et al. 2009, Ciccone et al. 2010). HF and DM management programs including patient empowerment and support, show better outcomes of adherence and help to promote confidence and enhance safety of chronic patient management at home.

Self-care management is a cognitive and behavioral process which refers to regular maintenance tasks like being adherent to medications, engaged in physical activity, following proper diet, monitoring weight gain and management of the symptoms (Riegel et al., 2004). The educational interventions, which involve patients' collaboration, seem to be more effective that the didactic ones in improving glycemic control, lipids and the weight of the patients. Evidence shows that the involvement of the patients according to their individual needs supports the effectiveness of self-care management, in chronic diseases (Lainscak et al., 2011). Therefore, a comorbidity approach to self-care education like focusing on behavior approach and developing strategies for maintaining the knowledge about the two diseases seems to be vital for HF-DM patients and more effective in achieving the proper adherence to therapy (Dunbar et al., 2015).

It is important that HPs do understand and recognize those challenges in self-care management of comorbid conditions and find strategies and ways to introduce empowerment in the care of the particular population and activate them to participate more in their health care management especially when ageing of population increases the prevalence of comorbidities.

5.2.5 Conclusions

Still, the main reason of deterioration is no adherence to the therapy and many patients feel they are not supported enough to do so. Patients with HF and DM are confronting serious challenges in self-care management of their comorbid condition.

5.2.6 Future directions

It is important that HPs do understand and recognize those challenges in self-care management of comorbid conditions and find strategies and ways to introduce empowerment in the care of the particular population and activate them to participate more in their health care management especially when ageing of population increases the prevalence of comorbidities. In addition, the era of the pandemic of COVID 19 emerged more than ever and researchers may contribute with interventional studies following similar methodology and evaluating same outcomes. A well-designed care may give the oportunity to the persons with HF and DM to enjoy the best possible quality of care. The relevant article is under review and is presented in Appendix II.

6. DEVELOPMENT OF INTERVENTIONAL PROGRAM 'SUPPORTHEART'

Based on the results from the systematic review and metasynthesis, the supportive needs of patients with HF were identified and contributed to the development of a 'guide' to be used for the focus groups. The focus groups extract more details and other informations that concered the supportive needs, as they were identified by the Cypriot patients with HF. The 'guide' developed is presented in Appendix III.

6.1 Focus Groups

Patients recruited from available contacts following convenience sampling. The first focus group of eight patients conducted and took place in the conference area of the Pancyprian Federation of Heart Diseases. The second focus group was consisted by three patients and took place in the Department of Nursing in the Cyprus University of

Technology. More patients were scheduled to attend but finally only three of them made it that day.

Participants of the focus groups were:

1) Patients who had been diagnosed with chronic HF (based on systolic or diastolic dysfunction) as diagnosed by a cardiologist,

2) NYHA classification stages I-IV,

3) The diagnosis had to be established for at least 6 months,

4) Patients should be able to understand, write and read Greek.

The focus groups were led by a nurse using the guide developed and designed to not exceed the one hour. Discussions were digitally recorded with the consent of the participants and field notes were taken as well. Focus groups discussions were transcribed from the audiotapes by a researcher. An electronic copy of each focus group data was given to each member of the team with the audiotaped recording**.** Each member of the research team read the transcripts of the audiotapes independently.Then they underlied important statements of the transcript, giving codes. At the second step of the analysis, the same four researchers were gathered and reviewed together the giving codes and agreed the final codes revealed from the transcript. Finally, researchers collaborated and grouped the important statements into major themes. Differences in coding of the themes were discussed by the researchers in order to reach consensus. From this process, the following themes were disclosed that cover the needs of patients with HF: ‘Self-care-management’, ‘palliative care’, ‘supportive care’, ‘social support’, Person Center Care (PCC) and ‘better health care services’.

SPECIFIC SECTION

7. AIM OF THE STYDY

Supportive care is the way that manage to empower the patients with HF-DM to take part in the management of their own condition because is the care that considers the tailored needs and values through the HF trajectory. The purpose of the current study was to evaluate the effectiveness of an individualized supportive care management program in patients with HF and DM, in order to improve patients' HR-QoL compared to the 'usual' care. This study is a sub-analysis of the randomized clinical trial (RCT) – 'SupportHeart'.

7.1 Hypothesis

The hypothesis of the current study was that supportive care is beneficial for HF and DM patients as compared to the 'usual care', in terms of HR-QoL.

7.2 Expected outcomes

The primary outcome was to explore the difference in HR-QoL between HF-DM patients receiving supportive care interventions compared to the 'usual care'.

The secondary outcomes were to investigate the difference between HF-DM patients receiving the supportive care interventions and 'usual care' in terms of:

- Self-management
- Knowledge and their adaption of the knowledge as a health care behavior
- Perceived social support
- Exercise tolerance (Self-reported measurement)
- Anxiety and depression
- Acute events (readmissions and emergency room visits) and mortality

7.3 Hypothesis Testing- Null hypothesis (Ho) and Alternative hypothesis (H1)

Null hypothesis (Ho): There is no difference between patients with HF-DM receiving supportive care intervention and HF-DM patients receiving standard care in terms of HR-QoL.

Alternative hypothesis (H1): There is positive effect in HR-QoL in HF-DM patients receiving supportive care interventions compared to HF-DM patients receiving supportive care.

8. RESEARCH METHODOLOGY

This chapter presents a detailed outline of the study methodology, taking into consideration methodology procedures used and undertaken for the establishment of the aim of the study. Operationalisation of the design, in terms of intervention development, data collection and analysis are presented. To promote transparency and integrity of this study, the ethical considerations and licenses that were undertaken are also included.

8.1 Type of study

The current study was a sub-analysis of the RCT named SupportHeart (Trial ID: NCT04415723) using pragmatic methodology. It was consisted by two groups: 1. The intervention group (IG) and 2. The control group (CG). The study investigated the patients for a period of 1 year at 5 time points (in baseline, 1 month, 3 months, 6 months, 1 year).

8.2 Sample of the study

The sample of the study consisted of patients from hospitals, patients who are included and receive services from the new National Health System of Cyprus and patients from the Pancyprian Federation of Heart Diseases, diagnosed with HF (HFpEF or HFrEF), established by a cardiologist with the comorbidity of diabetes mellitus.

8.2.1 Inclusion criteria

The inclusion criteria:

- Patients > 18 years old
- Patients diagnosed with HF and DM based on systolic or diastolic dysfunction as diagnosed by a cardiologist
- NYHA classification stages I-IV
- Patients able to understand write and read in Greek language

8.2.2 Exclusion criteria

The patients excluded from the study were:

- Patients who refused to take part in the research
- Patients diagnosed with any kind of mental illness
- Patients diagnosed with dementia
- Patients under hemodialysis
- Patients with whom telephone communication is not applicable
- Patients not speaking the Greek language
- Patients transfer to a nursing home after discharge

8.2.3 Sample size

The method of power analysis used to determine the sample size. Power analysis is the ability to find a statistically significant difference when the null hypothesis is in fact false. In other words, power is the ability to find a difference when a real difference exists. It is determined by three factors: the sample size, the alpha level, and the effect size (McHugh, 2008).

In the current study, researchers wanted to determine the appropriate sample size or justify a proposed sample size. In order to answer this question, researchers found out the other two parts of the equation: alpha level and effect size (McHugh, 2008).

In the RCT with the acronym, ‘SupportHeart’ the sample size consisted from 202 patients in total from which the 121 patients were those with HF and DM.

8.3 Pragmatic methodology

The word pragmatism originates from the Greek word “pragma”, that means action that is the central factor of pragmatism (Pansiri, 2005). Human actions can never be separated from the beliefs, values and previous experiences of people. Human thoughts and believes are related to human action and the results of the actions can be used or rejected by humans in the future (self-management actions on improvig signs and symptoms) (Goldkuhi, 2012). A pragmatic study focuses on an individual decision-making in a real-world situation like patients with HF and the commorbitidy of DM. The process of undertaking a pragmatic study is first the indentification of a problem (no adherence to the therapy and many patients with HF and DM feel are not supported enough despite the successfull management programmes developed earlier) and viewed this problem in a broadest context. This can lead to research inquiry that leads to find ways to better understand and solve the problem. A pragmatic approach can use different methods and techniques like mixed methodology. The pragmatists often try to understand the various factors that may involved and people act in a situation e.g what HF-DM patients do in hot weather when they are feeling thirsty or they are physically active in hot weather or fasting for spiritual purposes. Therefore, the pragmatists know that the theory will not lead to certainty because nothing in the world is certain and depends on various factors. A pragmatic theory avoids fixed primciples and solutions to a problem and is based on terms as are applicable to peoples’ experiences and are unique for each individual (individualised and patient-centred). Reality is not static and it changes at every turn of events so a pragmatic study is an evolutionary and no stable study (Goldkuhi, 2012).

8.4 Randomized Clinical Trial

8.4.1 Randomization

The random selection of subjects was used to ensure that the IG and CG are similar in all aspects with the exception of the beneficial measure being tested (Kabisch et al., 2011).

All participants of the RCT ‘SupportHeart’ were randomized to receive either the intervention care or the usual care, with a ration 2:1 using the sealed envelope technique by using random number generator.

A member of the research team who did not participated in the recruitment of the sample did the random distribution for the RCT SupportHeart of the participants in the two groups. The random allocation developed with the use of a software program. The researcher was blinded regarding the group allocation of the next patient so the prediction of the selection bias achieved by using closed envelops for the recruitment because the researcher opened the envelops after the patient agreed to participate in the research and signed the informed consent form.

8.4.2 Blinding

'Double blinding' could not be achieved because patients informed before signing the consent form to participate in the research. So, after opening the envelop, both; the patient and the researcher were aware in which group the patient were.

8.5 Ethical considerations

The participants signed an informed consent form where a detail description of the study presented (Appendix IV). It included the aim of the study, what was expected of them and the reasons why this study is important. Written informed consent was obtained from the participants at the beginning of the study ensuring anonymity and confidentiality. The study had a voluntary nature that allowed the patients to withdrawn at any time. The anonymity of the participants was respected throughout the study.

The study granted approval by the Cyprus Bioethics Committee and by the Data Protection Office (Appendix V). In addition, license was sought and granted, by the Scientific Committee for the Promotion of Research and the Ministry of Health of Cyprus (Appendix VI).

8.6 Study Development of the RCT ‘SupportHeart’

1. The first step of the ‘SupportHeart’ study design and intervention was the conduction of a qualitative research (Metasynthesis) in order to determine what HF (and DM) patients describe as major needs and which intervention was effective for them. The support needs extracted, served as a ‘guide’ to develop a plan to be used in the intervention**.** A systematic review and meta-analysis was also conducted to examine the potential effectiveness of supportive care interventions in improving the HR-QoL of patients with HF (Appendix.VII).

2. Focus groups exploring patients with HF views on their support needs were also conducted, to find out, if the literature reflects their needs or if specific aspects for their support needs are missing. The most important aspects of care were identified by patients’ questions. Two focus groups were conducted. Those patients were not hospitalized for at least one month. Results of the focus groups were used to create the educational program for the IG. The results developed were the following: **Self-management** was developed from the sub-themes of choosing health professionals and self-care actions, **palliative** care from the sub-themes of fear of death and anxiety and concern. **Supportive care** was developed from the sub-themes of interpersonal relationships and mediators, psychological support, multidisciplinary team, information and communication. **Social support** was consisted of the subthemes of lack of benefits from services, financial support and social services. **PCC** was made up of the sub-themes of recognition of the situation and acceptance, lifestyle modification and education. **Better health care services** theme was developed from the sub-themes of dissatisfaction of patients with clinical examination and follow-up, insufficient public sector services, time-consuming procedures and inadequate care by HPs. Only the last theme was different from the results of the meta-synthesis. The Colaizzi’s phenomenological method of analysis of the qualitative taped data and researcher notes was performed, to identify themes grounded in the responses.

3. Findings excracted from the focus groups used as a ‘guide’ for the ‘SupportHeart’ research team to deliver the intervention based on the four components of supportive care-communication, education, psychological & spiritual issues and symptom management (Goodlin et al., 2009). The type of mixed method used was the exploratory

sequential design where the quantitative phase of data collection and analysis follows the qualitative phase of data collection and analysis (Fetters, Curry & Creswell, 2013).

4. The quantitative phase of data collection followed, using the following tools: the Greek versions of the 'Minnesota Living with Heart Failure questionnaire' (MLHFQ), the 'Self-care of Heart Failure Index' (SCHFI), the 'Multidimensional scale of perceived social support' (MSPSS), the 'European Heart Failure Self-Care Behavior Scale' (Gr9EHFScB), the 'Hospital and Anxiety depression scale' (HADS), the 'International Physical Activity Questionnaire' (IPAQ), the 'Audit of Diabetes Dependency Quality of Life Version 19' (ADDQoL-19), socio-demographic and clinical variables of the participants.

The CG received the 'usual care.' 'Usual care' was defined as the actions that each hospital or health care setting follows for all patients before their discharge from the hospital/their personal doctor that includes general advice on managing HF and DM and following.

The IG received the supportive care management program developed, according to the themes arrived from the qualitative analysis of the focus groups (e.g monthly meetings, education, telephone support, SMS, etc.).

Follow-up: The follow up period was twelve months as this was considered a sufficient timeframe to observe the effectiveness of the supportive program to achieve the goals of the 'SupportHeart' research program.

It is very important a management program to be set and offers a structured pre-discharge care for patients with HF before patients' discharge (Phillips et al., 2005; Yu et al., 2006). According to Lambrinou et al. (2012) common factors for the in-hospital phase of HF management of the disease, are the total discharge planning and transition care; this was considered to be the case for patients with HF and DM. A member of the 'SupportHeart' research team invited the selected patients to take part in the study before hospital discharge - most of the participants recruitment from hospitals, through their cardiology from the new National Health System of Cyprus and through the Pancyprian Federation of Heart Diseases. The participants informed by the researcher about the various aspects of the study. They were informed about the purpose of the research and that they could interrupt their participation at any time they desired. It was highlighted their treatment would not be affected whether they participate in the research or not.

8.7 The ‘SupportHeart’ Program and the Intervention

‘SupportHeart’ research team was consisted from nurses specialized in HF care, a nurse specialized in DM care and a physiotherapist specialized in HF who collaborated with the rest of the HF team when needed. Coordinator of the ‘SupportHeart’ program was Professor Ekaterini Lambrinou from the Cyprus University of Technology. Patients with HF and DM were invited to participate in the study by a member of the reasearch team, just before their discharge/from the beginnig. Patients were informed for the context of the research and if they agreed to participate in the study, they signed a consent form. Data collection was conducted by the researchers during the monthly meetings or by phone.They used questionnaires and a guide that were pre-decided by the research team. The monthly meeting points and the main topic was predetermined by the research team. Beyond that, questions from the patients were resolved and there was also a discussion on other topics patients’ wanted to discuss and according to their needs. The current intervention program was based in pragmatic research methodology as referred above. In pragmatic studies an intensive intervention and treatment strategy of rapid-titration and close follow up is rapidly accepted by patients, like in the STRONG-HF study (Giuseppe et al. 2023). The basic characteristics of the intervention management program included:

● Early involvement of HF – DM patients in the intervention with rapid closed follow-up, based on a patient –centred approach.

● Monthly meetings where participants were educated about the syndrome of HF and the comorbidity of DM.

● Monthly meetings where participants were educated and supported through motivation about pharmacological, non - pharmacological therapy and self-management measures based on their tailored needs every time.

● Understanding the aspects of HF and DM and recognizing symptoms.

● Monitoring and recognizing the aggravation of signs and symptoms of the two diseases. Knowledge about the time that they should inform HPs.

● Daily recording of body weight and recognizing signs of overfload.

● Understanding the necessity and benefits of exercise.

● Understanding the doisage and expected results of medication and the importance of taking the prescribe medication regularly.

● Intake sodium reduction to reduce the fluid overload.

● Understanding the benefit of avoiding increased fluid intake to no more than 1,5-2 litres per day.

● Eating healthy foods and maintenance of normal body weight.

● Discussion of the significance of anxiety and depression and the way it affects self-management and about seeking help in time.

● Guidelines about holidays or travel during cold or hot weather.

● Guidelines about implantable devices.

● Guidelines about not to avoid the three main meals daily and the snack breaks between the main meals.

● Guidelines about early recognition of signs and symptoms of hypoglycaemia and ways to manage it.

● Guidelines about safe transfer of insulin/ oral DM and HF medications especially in hot weather.

● Guidelines about measurement and transferring glucose monitoring devices, blood pressure measurement devices and pulse oximeter.

● Guidelines about optimizing glycaemic control to reduce the risk of acute (hyporglycaemia/ hyperglycaemia) and chronic diabetic complicarions – microvascular (retinopathy, neuropathy and nephropathy), or macrovascular (cardiovascular, cerebrovascular and peripheral vascular disease).

● Guidelines about performing a foot evaluation to inspect the skin daily to identify any risk factors for ulcers.

● Organization of exercises, social events (day trip, meetings for coffee) and walking.

Every participant in the IG received a package as soon as they entered the program that contained:

● An educational booklet about daily aspects regarding HF management (Appendix VIII)

● A recording form with columns to daily record their weight, blood pressure, heart beats and glucose level (Appendix IX).

●A bullet form including the major educational points with the emergency signs and symptoms (Appendix X)

● A fridge magnet with the logo of ‘SupportHeart’ to attach the above forms, so that it reminded the participants to record the measurements daily and take a look on the emergency signs and symptoms for the patiens with HF and DM (Appendix XI).

A detailed description of the intervention is mentioned below. Patients that they entered in the IG received an educational booklet material and the first educational session by the researcher in the bedside of the patients before their discharge for hospitalized patients and right from the beginning for non - hospitalized patients. Then, the researcher was contacting via telephone the patients 48 hours after the first meeting, in order to find out how they are getting along and resolve any possible queries on HF and DM self-management. The first monthly meeting was arranged a month after the discharge / first meeting and patients were educated with the main themes regarding HF and DM. A monthly meeting was then arranged by the research team with the patients and their caregivers, which lasted about two hours. In the meetings, the patients were educated about the syndrome of HF and the comorbidity of DM and about pharmacological, non - pharmacological therapy and self-management measures. The non-pharmacological management is self-care management, which can be achieved through education (Lambrinou et al., 2014). The patients had to follow some life-style modifications in order to remain healthy and avoid acute events. The education included daily fluid volume, low sodium, fat and sugar free diet, monitor weight, physical activity, breathing techniques to have more effective breathing, daily and regular checking of blood glucose level, quitting smoking, managing fatigue, coping with psychological aspects, medication adherence, socializing, relaxation, early recognition of signs that aggravate HF and DM and reduce the HR-QL of the patients.

The model of Goodlin et al. (2004) for providing evidence-based disease modifying interventions in supportive care was used in the IG to assess the terms of the four components of supportive care for each patient (Table 1). The researcher during the monthly meetings was discussing with the patients various aspects about HF and DM management and issues the patients needed. The ‘SupportHeart’team was providing the appropriate knowledge and self-management skills to the participants based on their own condition. In addition, the researcher was contacting patients via phone calls and patients were empowered and discussed various issues that concerned them. The patients were able to call the researcher by phone whenever they wanted or needed to. After the first contact, in three- months, six-months and 12 months period, patients were conducted by phone call and assessment was established using questionnaires. Rregular communication supported patients to know how and when they should get help from HPs and follow-up check-up. In addition, they were educated how they should make changes regarding their lifestyle modification to reduce the risk of an acute event, build on their own strengths so they can increase their self-efficacy and self-confidence, understand the educational program and benefits of following it, self-manage themselves in a way that reduces the risk of decompensation and understand early signs of decompensation.

Supportive care through continuing communication is very important for patients with HF and DM; regular contacts help patients to develop their skills in self-management over time, whereas the unscripted aspect allows the coach to tailor support to the individual needs of each patient. In addition, the regular communication aims to provide support and encouragement to patients, promote healthy behaviors like treatment control, proper diet, physical activity and mobility (Hutchison and Breckon, 2011).

Regular communication is also important to support patients in the end stage of their life when individuals are unable to meet not only their physical needs, but also their psychosocial and spiritual needs (Goodlin 2009, Graven & Grant, 2014). Through continuing communication, the patients maintained their own health more independently and the nurse with the patient were able to identify problems before they become critical and ask for help (Birmingham East and North NHS, 2007).

The needs of patients with HF and DM are different each time and depend on their current state of illness and individual requirements (Klindworth et al., 2015). The supportive care from HPs can offer a total assessment and regular monitoring of the physical and psychosocial condition of the patients and meet the appropriate information needs and any concerns of patient and care (Boyd et al., 2010). The continuing individualized assessment through the supportive care program can offer to the patients but also to the HPs as well, the capacity of early recognition and take steps with the purpose to meet the needs of the patients according their own preferences.

In the therapeutic process of HF and DM, HPs must be able to coordinate and plan their care proactively, offer tailored information according to patients' needs and promote self-management (Boyd et al., 2010). Through the intervention process, a bond and a supportive relationship created among the HPs and the patients in the 'SupportHeart' program, so the communication was more effective. One of the factor influencing adhererence to the therapy is a good patient-HPs relationship that seems to improve clinical parameters of patients with HF and DM who show better control of their conditions so they can develop a 'partnership' between them, with which the patients gradually manage to feel motivated and self-confident (Philippou et al., under review).

Patients in the IG were advised to receive their prescribe medication unless they had hypotension or dizziness, so they could contact a member of 'SupportHeart' team or their doctor to get advice. Pharmacological education based on the recent ESC guidelines (McDonagh et al., 2021), included: Renin-angiotensin-aldosterone system blockers like Angiotensin Converting Enzyme Inhibitors (ACEIs) and Angiotensin Receptor Blockers (ARBs) which have the same treatment effects, in patients with HFrEF, with and without DM (Konstam et al. 2009, Zannad et al. 2011, McDonagh et al. 2021). One of the earliest neurohumoral changes in HF is sympathetic activation. Beta-blockers cause short period of sympathetic activation which increases peripheral perfusion by increasing heart beats and myocardial contractility (Chatterjee et al., 2013) Beta-blocker are used in patients with HFrEF and DM since are effective at reducing all-cause death and hospitalization for HFrEF in patients with DM (Deedwania et al., 2005). Ivabradine is another medication that blocks the channel responsible for the cardiac pacemaker current, I (f), which regulates heart rate. This, results in prolonged diastolic time and reduced heart rate (Pavasini et al.,2019). It improves the treatment of HFrEF in sinus rhythm, reduces HF hospitalization and improves LV function (Komajda et al., 2015). Digoxin increases intracellular sodium that will drive an influx of calcium in the heart and cause an increase in contractility. Digoxin may reduce the risk of HF hospitalization in HFrEF treated with

ACEIs although its effect on those routinely treated with beta-blockers has not been tested (Abdul-Rahim et al. 2016, Ren et al.2020, McDonagh et al. 2021). About diuretics, there is lack of evidence for the effectiveness of thiazide or loop diuretics in the reduction of CV outcomes in HF patients and their effects on morbidity and mortality have not been studied in RCTs (McDonagh et al., 2021). However, they are used in the treatment for HF-DM patients, because they prevent and treat symptoms and signs of fluid congestion in these patients (Ponikoswki et al., 2016, McDonagh et al. 2021). Oral glucose-lowering agents on heart failure include metformin, which has a glucose-lowering effect by inhibiting hepatic gluconeogenesis and opposing the action of glucagon (Eurich et al. 2005, Foretz et al. 2019). Sulfonylureas is another oral glucose-lowering medication that directly stimulate the release of insulin from beta cells of pancreas, lowering blood glucose (Pantalone et al., 2009). Thiazolidinediones is a drug that increases insulin sensitivity by acting on adipose, muscle, and to liver, to increase glucose utilization and decrease glucose production. (Dormandy et al., 2005). SGLT2 are the latest class of anti-hyperglycemic agents that found to be effective in HF patients with DM. It reduces renal tubular glucose reabsorption, producing a reduction in blood glucose without stimulating insulin release (Lu et al., 2021). When insulin started for DM2, usually is recommend "basal" insulin (Yki-Jarvinen et al., 2000). Most types of insulin that is used are the intermediate-acting or long-acting forms of insulin to keep blood sugar controlled overnight and during the day (Taylor et al., 2000). Basal insulin is usually started at a low dose (10 to 20 International Units subcutaneously) and then increased gradually to regulate the right dose for an individual depending on diet, exercise level and sensitivity to the effects of insulin, which is different from person to person (Taylor et al., 2000). When DM2 patients are using a combination of treatments (oral medication plus insulin) generally, the dose of insulin is low compared with taking insulin only (Yki-Jarvinen et al., 2000). Patients in the IG who were taking insulin were educated by the researcher who is specialized in the care and management of people with diabetes mellitus, on the special isues for insulin administration.

Non - pharmacological education included fluid and sodium management, fat and sugar free diet, physical activity, smoking caesetion and travel issues. The non-pharmacological education is presented in details in Appendix XII.

Table 1: The four components of supportive care in HF. (Goodlin SJ et al. Consensus statement: Palliative and supportive care in advanced heart failure. Journal of Cardiac Failure, 2004, 10(3), 200–209).

	Phase 1	**Phase 2**	**Phase 3**	**Phase 4**	**Phase 5**
	Initial symptoms of HF develop and HFtreatment is indicated	Initial medical management or following mechanical support or heart transplant	Functional status declines, intermitent exacerbations of HF that respond to rescue efforts	Stage D HF, with refractory symptoms are limited, End of life	
NYHA classification	**I-II**	**II-III**	**III**	**IV**	**IV**
Supportive Care **A.Communucation**	-Understand patient concerns and fears -Identify life-limiting nature of HF -Elicit preferences for care in emergencies or sudden death and for information and role in decision-making -Elicit symptoms and assess QoL	-Elicit symptoms and assess QoL -Re-evaluate resuscitation preference for care in emergencies -Set goals for care -Identify coping strategies -Re-educate about sodium,weigt and volume status	-Elicit symptoms and QoL -Elicit values and re-evaluate preferences -Identify present sratus and likely course(s) -Re-evaluate goals of care -Re-educate about sodium,weight and volume status,medication compliance	-Elicit symptoms Ackmowledge present status -Elicit preferences and reset goals of care -Identify worries -Review appropriate care options and likely course with each -Explore suitability and preferences about surgery or devices	-Elicit desired symptom reliefand identify medication for symptom goals -Assistance with he delivery of care -Preferences for end-of-life care ,family needs and capabilities -Plan after death(care of the body, notifications, memorials)

B.Education	-Patient and family self-management(Sodium,weight,voume) -Diet,exercise -HF course inc;uncluding sudden death and options fo management	-What to do un an emergency -Review self -management	-Review self –management -Review what to do in an emergency -Symptom management	-Optimal management for given care approach -Intervention for deterioration in status -What to do in an emergency	--Likely course and plans for management of events -Symptom management -What to do when death is near and at the time of death
C.Physical **& Spiritual issues**	-Coping with illness -Insurance and financial resources -Emotional and spiritual	-Roles and coping for payment and family -Emotional support -Spiritual support -Social interaction -Evaluate both patient and family anxiety and depression	-Family stresses and resources -Re-evaluate patient and family needs -Caregiver education and assistance with care	-Insurance coverage -Re-evaluate stresses, needs and support patient and family -Support coping with dying	For both patient and family: -Address anxiety, distress, depression -Address spiritual needs, concerns regarding dying -Anticipation grief support -Post –death bereavement

D.Symptom management	-HF medications for dyspnea -Exercise training for fatigue -Antidepressant for depression -Local treatment and opioids for pain	-Identify new or worsened symptoms -CPAP/O2 for seep -Exercise program(lower extremity)	-O2 for dyspnea -Lower extremity strengthening for dyspnea -CPAP/O2 for sleep	-O2for dyspnea -Opioids for dyspnea -Inspiratory strengthening -CPAP/O2 for sleep -Benzodiazepines/counseling for anxiety	-Opioids for dyspnea/pain -O2 for dysnea -Benzodiazepines/counseling for anxiety -CPAP/02 for sleep-disordered breathing -Simulant for depression

8.8. Quantitative data collection

8.8.1 Tools

The members of the research team of the ‘SupportHeart’ program gathered the quantitative data during the monthly meetings for the IG and by phone for the CG, using the following tools:

a) The Greek version of the ‘Minnesota Living with Heart Failure questionnaire’ (MLHFQ) which assesses HR – QoL (Rector et al. 1992, Lambrinou et al. 2013) (Appendix XIII)

b) The Greek version of the ‘Self-care of Heart Failure Index’ (SCHFI), which evaluate patients’ knowledge and their adaption of the knowledge as a health care behavior (Riegel et al. 2009, Lambrinou et al. 2022) (Appendix XIV).The translation and validation of the Greek version of the SCHFI was published (Appendix XV).

c) The Greek version of the ‘Multidimensional scale of perceived social support’ (MSPSS), which measures the perceived adequacy of the available amount of social support from friends, family and significant other/special person. (Zimet et al. 1988, Theophilou et al. 2015) (Appendix XVI).
d) The Greek version of the ‘European Heart Failure Self-Care Behavior Scale’ (Gr9EHFScB) measuring knowledge regarding HF (Jaarsma et al. 2009, Lambrinou et al. 2014) (Appendix XVII).
e) The Greek version of the ‘Hospital and Anxiety depression scale’ (HADS) measuring anxiety and depression (Zigmond & Snaith et al. 1983, Michopoulos et al. 2008) (Appendix XVIII).
f) The Greek version of the ‘International Physical Activity Questionnaire’ (IPAQ), measuring self-report measure of habitual physical activity (Craig et al. 2003, Papathanasiou et al. 2009) (Appendix XIX).
g) The Greek-Cypriot version of the questionnaire Audit of Diabetes Dependency Quality of Life Version 19 (ADDQoL-19), a specialized instrument that evaluates the effect of diabetes in the QoL (Bradley, 1994) (Appendix XX).
h) Measurement of acute events; readmission and mortality (Appendix XXI).
i) Socio-demographic and clinical variables of the participants (Appendix XXII).

8.8.1.1 Description of questionnaires

***Minnesota Living with Heart Failure Questionnaire* (MLHFQ)**

It is one of the most widely used questionnaires measuring HR-QoL in HF population and has been translated and culturally adapted into at least 34 languages, demonstrating good psychometric properties (Bilbao et al., 2016). The Greek version consists of 21 items using a 6-point Linkert scale (0-5), with score ranging from 0-105, higher scores indicte poorer HR-QoL (Lambrinou et al., 2013). The Greek validation of the MLHFQ provided a 3-factor solution explaining the 64.15% of the variance (physical, emotional and social subscales) (Lambrinou et al., 2013).

Self-care of Heart Failure Index (SCHFI)

This is a 22-item instrument with three scales. The scales are the components consisting HF self-care; maintenance, management and confidence (Riegel et al., 2009). Section A asks patients how frequently they utilize self-care maintenance behaviors to manage HF, section B asks patients how often they have experienced trouble breathing or ankle swelling and section C measures how confident are patients practicing self-management of HF (Riegel et al., 2004). Each scale uses a 4-point self-report response format: 1 (never or rarely), 2 (sometimes), 3 (frequently), 4 (always or daily). Each scale score is standardized to a 0 to 100 range; higher scores indicate better self-care. Authors refer a cut-point of ≥70 on each scale of the tool to judge self-care adequacy. The tool is updated and the used form of the tool is the sixth version (Riegel et al., 2009). The questionnaire was translated into Greek and socioculturally adopted in the Greek population. Psychometric properties of the Greek version showed that the Cronbach's alpha index and the Composite reliability index had satisfactory internal coherence indicators (Cronbach's alpha 0.80-0.92, and Composite reliability 0.88-0.96, respectively) (Lambrinou et al., 2022).

Multidimensional scale of perceived social support (MSPSS)

The MSPSS is a 12- item questionnaire, measuring the perceived adequacy of the available amount of social support from friends, family and significant other/special person. All questions are rated in a seven-point Likert scale; with responses ranging from very strongly disagree (=1) to very strongly agree (=7). The total scores range from 12 to 84, with higher score reflecting higher amount of available social support (Dahlem et al., 1991; Dambi et al., 2018). The questionnaire has good psychometric properties and have been adopted and translated in more than fifteen different languages (Dambi et al., 2018), among them in Greek language as well (Theophilou, 2015). This questionnaire was also checked for the population of HF and is found to be reliable and valid instrument to measure perceived social support in patients with HF (Chamboulidou et al. 2016, Shumaker et al. 2017).

European Heart Failure Self-Care Behavior Scale (Gr9-EHFScBS)

The Greek version of the 9- item European HF Self-Care Behavior Scale (Gr9-EHFScBS) uses a 5-point Likert-type scale with 1 equaling ‘I completely agree’ and 5 equaling ‘I do not agree at all’, measuring HF related self-care behaviors. The total score is calculated by summing the ratings for each item. The total score ranges from 9 to 45 with higher scores indicating poorer self-care behaviors. Gr9-EHFScBS is better supported by a one-factor model and it preferable yo be used as a whole (Lambrinou & Middleton, 2015).

The Greek version of the tool has acceptable psychometric testing (Lambrinou et al., 2014).

Hospital and Anxiety depression scale (HADS)

The HADS is a screening questionnaire developed by Zigmond and Snaith (1983) aiming to detect clinically significant anxiety and depressive symptoms in patients (Zigmond & Snaith., 1983). The questionnaire is consisted of two subscales; one measuring anxiety and the other depression, each consisting of 7 items. There are two ways of interpreting the HADS scores; either by comparing an individual's score to normative values obtained from a sample of the general population, or by using cut-off scores that indicate different levels of clinically relevant distress. In the latter way, three cut-off levels are used: a score between 8 and 10 indicate a mild case, 11–14 a moderate case and 15 or above, a severe case (Snaith & Zigmond. 1994, Crawford et al. 2001). The Greek version of the questionnaire performed by Michopoulos et al. (2008), shows good psychometric properties The HADS presented high internal consistency; Cronbach's α cofficient was 0.884 (0.829 for anxiety and 0.840 for depression) and stability (test-retest intraclass correlation coefficient 0.944). Factor analysis showed a two-factor structure. The HADS also, showed high concurrent validity; the correlations of the scale and its subscales with the BDI and the STAI were high (0.722 – 0.749) (Michopoulos et al., 2008).

International Physical Activity Questionnaire (IPAQ)

IPAQ can be assessed using subjectively or objectively. The subject measure using questionnaires is easier. This questionnaire developed to measure health-enhancing physical activity covering most daily situations. The IPAQ covers four domains of physical activity: work-related, transportation, housework/gardening and leisure-time activity. The questionnaire also includes questions about time spent sitting as an indicator of sedentary behaviour. In each of the four domains, the number of days per week and time per day spent in both moderate and vigorous activity are recorded. At work, during transportation and in leisure time, walking time is also included (Craig et al., 2003, The International Physical Activity Questionnaire. 2005). In recent studies, the IPAQ seems to be used most often and it is by far the most widely validated questionnaire at present (Van Poppel et al., 2010). The Greek version of the IPAQ is found to have acceptable reliability properties, showed high repeatability values for total and vigorous physical activity and good values for moderate and walking physical activity (Papathanasiou et al., 2009).

Audit of Diabetes Dependency Quality of Life (ADDQoL-19)

The ADDQoL-19 is a modification of the ADDQoL-18 (Bradley & Speight, 2002), which in turn was modified from the ADDQoL-13 (Bradley et al., 1999). Changes included:

1. Simplification of the instructions, clarification and restructuring of the *Not applicable* option by having explicit questions at the start of the item,
2. Those people for whom an item is not applicable are guided to go straight to the next item, instead of having to read other response options to find the N/A option,
3. Clarification of the part (b) statement of the preceding the importance skating range from *This aspect of my life is, to (For example) For me having a working life is,*
4. Division of one item into two items: holidays or leisure activities is now two separate items,
5. Addition of one new item namely closed personal relationship,
6. Deletion of one item namely *my enjoyment of food*, now covered by *my freedom to eat as I wish.*

Evidence for reliability, validity and responsiveness is well established for the English version and for translations. Translations are available in more than 20 languages, with further linguistic validation work in progress. The Greek for Cyprus version was established from standard UK English rev. 1.3.2006. for use under License Agreement CB151.

8.9 Analysis of the results

8.9.1 Statistical Analysis (Quantitative Analysis)

Descriptive statistics were used to present the results. Baseline characteristics were compared using independent samples Welsch t-test when the variables were continuous (i.e. age, hba1c) and the Fisher's exact test in the case of categorical variables (i.e. gender, comorbidity, etc.). Comparisons between IG and CG at each time point were assessed using a Welsch t-test. Comparisons of lost to follow- up between the two groups, as well as the comparisons of the numbers of acute events between the two groups, were assessed using the Fisher's exact test.

For the effect of the intervention on the Scales' scores (e.g. MLHFQ, ADDQoL, HADS, etx.) Linear Mixed Models Efects (LMME) were performed with the level of the scale as the dependent variable, and independent variables the group (CG, IG), the time-point (baseline, 1 month, 3 months, 6 months, 1 year) and the interaction between Group and Time-point (Group X Time). The models were also adjusted by the age, sex, NYHA classification, HbA1c level, etc of the participant. Statistically significant interaction term Group X Time, indicates that the trajectory of scale's score is different between the groups thoughout the study period - hence an effect of the intervention.

Using the LMME approach enabled researchers to deal with the following challenges:

1. Participant drop-out. The study stratified 121 patients for a period of 1 year at 5 time points (baseline, 1 month, 3 months, 6 months, and 1 year). LMME models did not drop the patients from the analysis; rather it considered all the observations up to the point of the drop out.

2. Intra-subject correlation of response measurements. This is true for nearly all longitudinal studies. The levels of the Scales of the current study was measured repeatedly for each patient, therefore, there was a correlation in the measurement within each subject. That way, if such correlation was ignored inferences such as statistical tests or confidence intervals can be invalid.

Reliability of the Scales was measured using the internal consistency index of Cronbach's alpha. Cronbach's alpha values greater than (>) 0.70 are considered to be satisfactory.

8.9.2 Qualitative analysis

Tapes from the focus groups were transcribed verbatim, and the Colaizzi's phenomenological method of analysis of the qualitative taped data and researcher notes was performed, to identify themes grounded in the responses (Colaizzi's, 1978). Three researchers examined the transcripts independently to identify themes, drawing upon a grounded theory approach. The three researchers then examined the transcripts holded a discussion to reach consensus on the predominant themes from the focus groups.

The phenomenological data analysis of Colaizzi includes the following steps:

1. Transcribe audiotapes verbatim immediately after the interview and read/listen to the interview in its entirety to gain a sense of the whole.

2. Extract significant statements from each transcript.

3. Formulate meanings as they emerge from the significant statements using significant insight.

4. Organize formulated meanings into clusters of themes. Validate the clusters of themes by referring back to the original transcript to ensure no data has been ignored or added to.

5. Integrate the results into an exhaustive description of the topic being studied.

6. Formulate the essential structure of the phenomenon.

7. Validate the descriptive results by returning back to the participants to confirm if this analysis describes their experience (If any data is deleted or added to, this new data is incorporated into the final product) (Colaizzi, 1978).

9. RESULTS

This section presents the missing values, lost to follow up, demographic and clinical characteristics of the participants and the findings of the current study.

9.1 Missing Values

Missing values on the scales were imputed using the multiple imputation algorithm (MI). The MI algorithm imputes the missing data points by predicting their value based on the values of the other observed data points, using a statistical model. The percentage of missing values per Scale and per time-point is shown below.

9.1.1 Missing values of the ADDQoL

ADDQoL has 36 items (excluding the 5 items about work and sex life). Missing values ranged from 2.8% in the baseline, to 5.4% at 1 year after the intervention (Table 2).

Table 2: Number of participants with missing values for ADDQoL

Time	Values missing	Number of patients	Scale Items	Pct Missing
baseline	120	121	36	2.8%
1 month	156	120	36	3.6%
3 months	138	113	36	3.4%
6 months	167	107	36	4.3%
1 year	193	100	36	5.4%

9.1.2 Missing values of the GR9EHFScBS

GR9EHFScBS missing values ranged from 0.2% at 3 months, to 0.9% at 1 year after the intervention (Table 3).

Table 3: Number of participants with missing values for GR9EHFScBS

Time	Values missing	Number of patients	Scale Items	Pct Missing
baseline	14	121	9	1.3%
1 month	4	120	9	0.4%
3 months	2	113	9	0.2%
6 months	3	107	9	0.3%
1 year	8	100	9	0.9%

9.1.3 Missing values of the HADS

HADS missing values ranged from 0% at 3 months, to 3.6% at 1 year after the intervention (Table 4).

Table 4: Number of participants with missing values for HADS

Time	Values missing	Number of patients	Scale Items	Pct Missing
baseline	39	121	14	2.3%
1 month	8	120	14	0.5%
3 months	0	113	14	0.0%
6 months	7	107	14	0.5%
1 year	51	100	14	3.6%

9.1.4 Missing values of the IPAQ

IPAQ missing values ranged from 0% in the baseline, to 9.9% at 1 year after the intervention (Table 5).

Table 5: Number of participants with missing values for IPAQ

Time	Values missing	Number of patients	Scale Items	Pct Missing
baseline	0	121	11	0.0%
1 month	58	120	11	4.4%
3 months	30	113	11	2.4%
6 months	78	107	11	6.6%
1 year	99	100	11	9.0%

9.1.5 Missing values of the MLHFQ

MLHFQ missing values ranged from 1.5% in the baseline, to 0.3% at 1 year after the intervention (Table 6).

Table 6: Number of participants with missing values for MLHFQ

Time	Values missing	Number of patients	Scale Items	Pct Missing
baseline	38	121	21	1.5%
1 month	34	120	21	1.3%
3 months	6	113	21	0.3%
6 months	26	107	21	1.2%
1 year	7	100	21	0.3%

9.1.6 Missing values of the MSPSS

In MSPSS there were lots of missing values (Table 7).

Table 7: Number of participants with missing values for MSPSS

Time	Values missing	Number of patients	Scale Items	Pct Missing
baseline	39	121	12	2.7%
1 month	205	120	12	14.2%
3 months	168	113	12	12.4%
6 months	4	107	12	0.3%
1 year	6	100	12	0.5%

9.1.7 Missing values of the SCHFI

In SCHFI, missing values ranged from 2.3% at 6 months, to 0.4% at 3 months after the intervention (Table 8).

Table 8: Number of participants with missing values for SCHFI

Time	Values missing	Number of patients	Scale Items	Pct Missing
baseline	49	121	22	1.8%
1 month	17	120	22	0.6%
3 months	10	113	22	0.4%
6 months	53	107	22	2.3%
1 year	13	100	22	0.6%

9.2 Lost to Folllow Up

Study started with 65 patients with HF and DM in the CG and 56 patients with HF and DM in the IG. At the end of the study, 10 (15.4%) participants were lost to follow-up in the CG, and 11 (19.6%) in the IG. No statistically significant difference was observed in the lost to follow-up across the two groups (p = 0.83). The number of patients at each time point are presented in Table 9.

Table 9: Number of patients at each time point

Time point	Control	Intervention
baseline	65	56
1 month	64	56
3 months	61	52
6 months	58	49
1 year	55	45

9.3 Demographic and Clinical Characteristics

The sample consisted of 121 patients: 80 (66%) male and 41 (34%) female patients with HF and DM. The mean age of the patients was $\bar{x}$ =73.9 (SD = 9.1) years old. Most of the patients were married (55%) and 33% were widowers. Regarding the educational level 56 (46%), 45 (37%) and 11 (9.1%) patients had elementary, secondary and higher education, respectively. Thirty-two patients (26%) had a history of myocardial infarction. All patients had DM2. All demographic characteristics of the participants are shown in Table 10.

The majority of the participants (N = 91 - 75%) had the underlying disease of CAD, 35 (29%) had acute arrythmias, and 22 (18%) had chronic atrial fibrillation. Forty-six (71%) participants who had CAD was found in the CG and forty-five (80%) was found in the IG (p= 0.2). Seventeen participants (26%) in the CG had acute arrhythmias and 18 (32%) with acute arrhythmias were in the IG (p= 0.5). Twelve (21%) of the participants in the IG had chronic atrial fibrillation and 10 (15%) were found in the CG (p=0.4). The most frequent risk factor from the clinical characteristics was hypertension [94 (78%)], with higher incidence in the CG [56(86%)] compared with the IG [38(68%)] (p= 0.016). Similarly, the second more frequent co-existing risk factor was hyperlipidemia which was present in 74 patients with the higher incidence in the IG [37 (66%)] compared with the CG [37 (57%)] (p=0.3). The third risk factor was obesity [19 (16%)] with higher incidence in the CG [11 (17%)] compared with the

IG [8 (14%)] (p= 0.7). Most of the patients 97(80%) were not active smokers. There were no patients at NYHA I in the current study. Most of the patients were at NYHA stage III [69 (57%)] [CG 35 (54%) and IG 34 (61%)] (p= 0.2). HbA1c levels was 7.5 % (0.7) in the CG and 7.1% (0.5) in the IG (p=0.005).

All clinical characteristics are presented in Table 11.

Table 10: Demographic characteristics of the participants ([1]Mean (SD); n (%), [2]Welch Two Sample test; Pearson's Chi-squared test; Fisher's exact test)

Characteristic	**Overall,** N= 121[1]	**Control,** N= 65[1]	**Interventiom,** N= 56[1]	**p-value**[2]
Age	73.9 (9.1)	75.6 (7.5)	71.9 (10.3)	0.026
Sex				0.055
Male	80 (66%)	38 (58%)	42 (75%)	
Female	41 (34%)	27 (42%)	14 (25%)	
Education				0.2
Higher	11 (9.1%)	4 (6.2%)	7 (12%)	
Secondary	45 (37%)	20 (31%)	25 (45%)	
Elementary	56 (46%)	35 (54%)	21 (38%)	
Family Status				0.7
Divorsed	5 (4.1%)	3 (4.6%)	2 (3.6%)	
Single	2 (1.7%)	1 (1.5%)	1 (1.8%)	
Married	66 (55%)	32 (49%)	34 (61%)	
Widowers	40 (33%)	23 (35%)	17 (30%)	
History of MI				0.4

Yes	32 (26%)	15 (23%)	17 (30%)	
No	89 (74%)	50 (77%)	39 (70%)	

Table 11: Clinical characteristics of the participants

(^{1}Mean (SD); n (%) ^{2}Welch Two Sample test; Pearson's Chi-squared test; Fisher's exact test)

Characteristic	**Overall,** N= 121^1	**Control,** N= 65^1	**Interventiom,** N= 56^1	**p-value**^{2}
Coronary artery disease	91 (75%)	46 (71%)	45(80%)	0.2
Acute arrhythmias	35 (29%)	17 (26%)	18 (32%)	0.5
Chronic AF	22(18%)	10 (15%)	12(21%)	0.4
Hypertension	94(78%)	56(86%)	38(68%)	0.016
Hyperlipidemia	74(61%)	37(57%)	37(66%)	0.3
Obesity	19(16%)	11(17%)	8(14%)	0.7
HbA1c	7.3(0.7)	7.5(0.7)	7.1(0.5)	0.005
LV- EF	36.8(8.6)	38.7(8.8)	34.6(7.9)	0.009
Active smoking				>0.9
No	97(80%)	52(80%)	45(80%)	
Yes	24(20%)	13(20%)	11(20%)	
NYHA				0.2

I	0(0%)	0(0%)	0(0%)
II	28(23%)	19(29%)	9(16%)
III	69(57%)	35(54%)	34(61%)
IV	24(20%)	11(17%)	13(23%)

9.4 Health Related Quality of Life

HR-QoL was measured using the Minessota Living with Heart Failure questionnaire (MLHFQ) in three dimensions: emotional, physical and social. At baseline, IG had higher physical (p = 0.12) with three points better compared with the CG, higher emotional (p=0.011) and no difference in the social HR-QoL (p >0.9) compared to the GC (Table 12). At 1st month, CG showed better HR- QoL in all the three dimensions of the MLHFQ compared to the IG (Table 13). At 3 months, 6 months and one year, the IG showed better HR-QoL compared to the CG in all the dimensions of the MLHFQ with exception the social dimension at 6 months which was the same for the two groups (p=0.8). At three months, IG had better HR-QoL in the physical dimension (p=0.3), emotional (p=0.012) and social (p=0.14) compared to the CG (Table 14). At six months IG had better HR-QoL in the physical dimension (p=0.11) and in emotional dimension (p=0.037), with no difference for the two groups in the social dimension (p=0.8) (Table 15). In one year after the intervention IG showed better HR-QoL in all the dimensions of the MLHFQ; physical (p=0.015), emotional (p=0.023) and social (p=0.4) (Table 16). The MLHFQ means plot x̄s are hown in Figure 2.

The multilevel model for the effect of the intervention on HR-QoL has shown a statistically significant effect of the IG at all time points after the intervention (p ‹ 0.001) on the overall HR- QoL (Table 17). Linear Mixed Model results have shown that there is a statistically significant effect in the IG at all time points after the intervention (p ‹ 0.001) in all the dimension of MLHFQ; physical, emotional and social HRQoL (Tables 18, 19, 20 respectively).

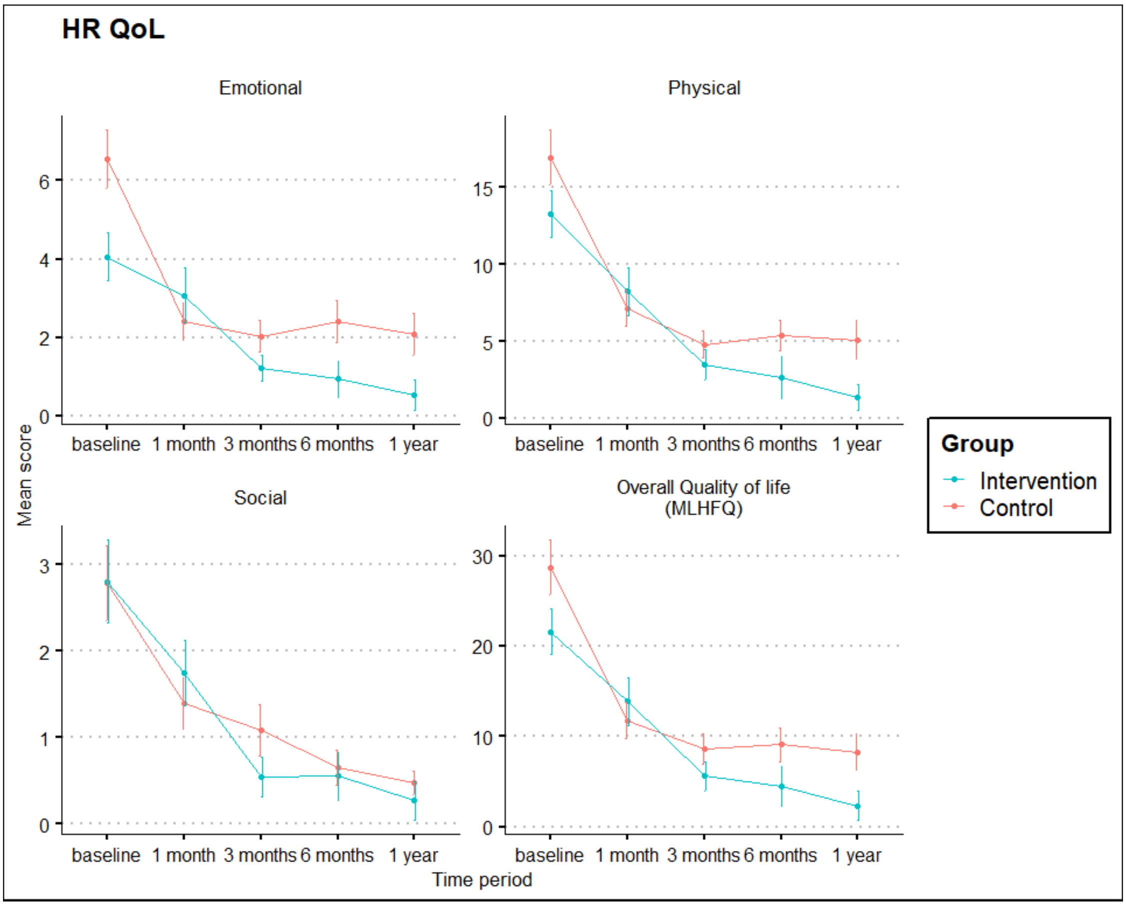

Figure 2: MLHFQ means plot HR- QoL

Note: LOWER scores indicate BETTER quality of life

Table 12: Health related quality of life at baseline

Dimension	**Overall**, N = 121[1]	**Control**, N = 65[1]	**Intervention**, N = 56[1]	**p-value**[2]
Physical	15.2 (13.0)	17.0 (14.2)	13.3 (11.2)	0.12
Emotional	5.4 (5.5)	6.5 (5.9)	4.1 (4.6)	0.011
Social	2.8 (3.5)	2.8 (3.5)	2.8 (3.6)	>0.9
Overall Quality of life (MLHFQ)	25.4 (22.2)	28.7 (24.1)	21.6 (19.2)	0.077

[1] Mean (SD)

Dimension	**Overall**, N = 121[1]	**Control**, N = 65[1]	**Intervention**, N = 56[1]	**p-value**[2]

[2]Welch Two Sample t-test

Table 13 :Health related quality of life at 1 Month

Dimension	**Overall**, N = 120[1]	**Control**, N = 64[1]	**Intervention**, N = 56[1]	**p-value**[2]
Physical	7.7 (10.3)	7.1 (9.3)	8.3 (11.5)	0.6
Emotional	2.7 (4.5)	2.4 (3.8)	3.1 (5.2)	0.4
Social	1.6 (2.6)	1.4 (2.3)	1.7 (2.8)	0.5
Overall Quality of life (MLHFQ)	12.8 (17.6)	11.8 (15.9)	13.9 (19.6)	0.5

[1]Mean (SD)

[2]Welch Two Sample t-test

Table 14: Health related quality of life at 3 months

Dimension	**Overall**, N = 113[1]	**Control**, N = 61[1]	**Intervention**, N = 52[1]	**p-value**[2]
Physical	4.2 (6.9)	4.8 (6.9)	3.5 (7.0)	0.3
Emotional	1.7 (2.8)	2.0 (3.1)	1.2 (2.4)	0.12
Social	0.8 (2.0)	1.1 (2.3)	0.5 (1.6)	0.14
Overall Quality of life (MLHFQ)	7.2 (12.2)	8.6 (13.0)	5.6 (11.2)	0.2

[1]Mean (SD)

[2]Welch Two Sample t-test

Table 15: Health related quality of life at 6 months

Dimension	**Overall**, N = 107[1]	**Control**, N = 58[1]	**Intervention**, N = 49[1]	**p-value**[2]
Physical	4.1 (8.7)	5.4 (7.7)	2.6 (9.6)	0.11
Emotional	1.7 (3.7)	2.4 (4.0)	0.9 (3.2)	0.037
Social	0.6 (1.7)	0.6 (1.6)	0.6 (1.9)	0.8
Overall Quality of life (MLHFQ)	7.0 (14.9)	9.1 (13.9)	4.5 (15.6)	0.11

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 16: Health related quality of life at 1 year

Dimension	**Overall**, N = 100[1]	**Control**, N = 55[1]	**Intervention**, N = 45[1]	**p-value**[2]
Physical	3.4 (8.0)	5.1 (9.2)	1.4 (5.6)	0.015
Emotional	1.4 (3.5)	2.1 (4.0)	0.5 (2.6)	0.023
Social	0.4 (1.2)	0.5 (1.0)	0.3 (1.5)	0.4
Overall Quality of life (MLHFQ)	5.6 (13.6)	8.3 (15.1)	2.3 (10.7)	0.024

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 17: LMME (Linear Mixed Model Effect) for the effect of the Intervention on the overall

Effect	**Beta**	**95% CI**[1]	**p-value**
Group			
Control	—	—	
Intervention	-6.5	-13, -0.43	0.036
Time point			
baseline	—	—	
1 month	-18	-23, -13	<0.001
3 months	-22	-27, -16	<0.001
6 months	-18	-24, -12	<0.001
1 year	-20	-25, -14	<0.001
Age	-0.16	-0.38, 0.05	0.14
Sex			
Male	—	—	
Female	-0.41	-4.5, 3.7	0.8
Ejection Fraction (EF)	-0.19	-0.42, 0.04	0.10
HbA1c	4.5	1.6, 7.4	0.003
NYHA			
II	—	—	
III	2.3	-2.1, 6.7	0.3
IV	2.6	-3.3, 8.6	0.4
Alcoholic	-5.4	-17, 6.7	0.4

Effect	**Beta**	**95% CI[1]**	**p-value**
Obesity	0.48	-4.6, 5.5	0.9
Smoking	1.6	-2.8, 6.1	0.5
Hyperlipidemia	0.19	-3.6, 4.0	>0.9
Hypertension	2.5	-2.1, 7.2	0.3
Arrythmias	0.15	-3.6, 3.9	>0.9
Valvular disease	0.88	-5.2, 6.9	0.8
Coronary artery	-4.9	-9.4, -0.34	0.035
Group * Time point			
Intervention * 1 month	9.8	2.0, 18	0.014
Intervention * 3 months	6.3	-1.7, 14	0.12
Intervention * 6 months	1.1	-7.1, 9.4	0.8
Intervention * 1 year	1.6	-6.5, 9.7	0.7
[1]CI = Confidence Interval			

Table 18: Linear Mixed Model Effect (LMME) for the effect of the Intervention on the physical health related quality of life

Effect	**Beta**	**95% CI**[1]	**p-value**
Group			
Control	—	—	
Intervention	-3.3	-6.8, 0.31	0.073
Time point			
baseline	—	—	
1 month	-11	-14, -7.5	<0.001
3 months	-13	-16, -9.7	<0.001
6 months	-11	-14, -7.2	<0.001
1 year	-11	-15, -8.2	<0.001
Age	-0.08	-0.21, 0.04	0.2
Sex			
Male	—	—	
Female	-0.70	-3.1, 1.7	0.6
Ejection Fraction (EF)	-0.10	-0.23, 0.04	0.2
HbA1c	2.8	1.1, 4.5	0.001
NYHA			
II	—	—	
III	1.1	-1.5, 3.7	0.4
IV	1.4	-2.2, 4.9	0.4
Alcoholic	-2.5	-9.7, 4.6	0.5

Effect	**Beta**	**95% CI[1]**	**p-value**
Obesity	-0.37	-3.4, 2.6	0.8
Smoking	0.71	-1.9, 3.3	0.6
Hyperlipidemia	0.24	-2.0, 2.5	0.8
Hypertension	1.2	-1.5, 4.0	0.4
Arrythmias	-0.10	-2.3, 2.1	>0.9
Valvular disease	0.63	-3.0, 4.2	0.7
Coronaryartery	-3.0	-5.7, -0.30	0.030
Group * Time point			
Intervention * 1 month	5.5	0.94, 10	0.018
Intervention * 3 months	3.5	-1.1, 8.2	0.14
Intervention * 6 months	0.03	-4.8, 4.8	>0.9
Intervention * 1 year	0.27	-4.5, 5.0	>0.9

[1] CI = Confidence Interval

Table 19: Linear Mixed Model Effect (LMME) for the effect of the Intervention on the emotional health related quality of life

Effect	**Beta**	**95% CI**[1]	**p-value**
Group			
Control	—	—	
Intervention	-2.3	-3.8, -0.83	0.002
Time point			
baseline	—	—	
1 month	-4.3	-5.7, -2.9	<0.001
3 months	-4.9	-6.3, -3.5	<0.001
6 months	-3.8	-5.3, -2.3	<0.001
1 year	-4.3	-5.7, -2.9	<0.001
Age	-0.04	-0.09, 0.01	0.2
Sex			
Male	—	—	
Female	0.05	-0.91, 1.0	>0.9
Ejection Fraction (EF)	-0.05	-0.10, 0.01	0.079
HbA1c	0.93	0.24, 1.6	0.008
NYHA			
II	—	—	
III	0.60	-0.42, 1.6	0.2
IV	0.55	-0.84, 1.9	0.4
Alcoholic	-1.5	-4.2, 1.3	0.3

Effect	Beta	95% CI[1]	p-value
Obesity	0.60	-0.57, 1.8	0.3
Smoking	0.15	-0.88, 1.2	0.8
Hyperlipidemia	-0.25	-1.1, 0.63	0.6
Hypertension	0.74	-0.33, 1.8	0.2
Arrythmias	0.20	-0.68, 1.1	0.7
Valvular disease	0.07	-1.3, 1.5	>0.9
Coronary artery	-1.2	-2.2, -0.10	0.033
Group * Time point			
Intervention * 1 month	3.0	0.97, 5.0	0.004
Intervention * 3 months	2.2	0.13, 4.2	0.037
Intervention * 6 months	0.79	-1.3, 2.9	0.5
Intervention * 1 year	1.0	-1.0, 3.1	0.3

[1] CI = Confidence Interval

Table 20: Linear Mixed Model Effect (LMME) for the effect of the Intervention on the social health related quality of life

Effect	**Beta**	**95% CI**[1]	**p-value**
Group			
Control	—	—	
Intervention	-0.03	-0.92, 0.85	>0.9
Time point			
baseline	—	—	
1 month	-1.5	-2.3, -0.76	<0.001
3 months	-2.0	-2.8, -1.2	<0.001
6 months	-2.2	-3.0, -1.3	<0.001
1 year	-2.3	-3.1, -1.5	<0.001
Age	-0.03	-0.06, 0.00	0.065
Sex			
Male	—	—	
Female	0.09	-0.52, 0.71	0.8
Ejection Fraction (EF)	-0.03	-0.07, 0.00	0.062
HbA1c	0.43	0.00, 0.86	0.050
NYHA			
II	—	—	
III	0.36	-0.31, 1.0	0.3
IV	0.43	-0.46, 1.3	0.3
Alcoholic	-1.1	-2.9, 0.71	0.2

Effect	**Beta**	**95% CI[1]**	**p-value**
Obesity	0.03	-0.73, 0.78	>0.9
Smoking	0.49	-0.17, 1.2	0.15
Hyperlipidemia	0.12	-0.45, 0.69	0.7
Hypertension	0.42	-0.28, 1.1	0.2
Arrythmias	0.03	-0.54, 0.59	>0.9
Valvular disease	0.07	-0.83, 0.97	0.9
Coronary artery	-0.34	-1.0, 0.34	0.3
Group * Time point			
Intervention * 1 month	0.44	-0.68, 1.6	0.4
Intervention * 3 months	-0.14	-1.3, 1.0	0.8
Intervention * 6 months	-0.17	-1.3, 1.0	0.8
Intervention * 1 year	-0.16	-1.3, 1.0	0.8
[1]CI = Confidence Interval			

9.5 Self-care Management

Self –care management was measured with two tools: the ‘Self-care of Heart Failure Index’ (SCHFI), which evaluate patients’ using knowledge and their adaption of the knowledge as a health care behavior (Riegel et al., 2009) and with the ‘European Heart Failure Self-Care Behavior Scale’ (Gr9EHFScBS) measuring knowledge regarding HF (Jaarsma et al. 2009, Lambrinou et al. 2014). The average scores across time, for the self -care dimensions of the SCHFI and the self -care dimensions of the Gr9EHFScBS are shown in Figures 3 and 4, respectively.

At baseline, in one month, in three months, in six months and in one-year IG was found to have higher self-care attitudes in all SCHFI dimensions ($p < 0.001$): the dimension of maintenance, management and self-confidence (Tables 21,22,23,24,25) respectively. The Linear Mixed Model for the effect of the intervention on the total self-care score for the SCHFI have showed a statistically significant effect of the intervention at all the time points after the intervention ($p < 0.001$) in the overall self-care (Table 26).The Linear Mixed Model results have also shown that there is a statistically significant effect of the intervention at all the time points after the intervention ($p < 0.001$) in all the dimensions of the SCHFI; the maintenance, management and self-confidence dimension (Tables 27,28,29 respectively).

At baseline, at one month, three months, six months and in one year, the IG showed higher self- care attitudes in all Gr9EHFScBS dimensions ($p < 0.001$): in the dimension of adhering to recommendations, fluid and sodium management, and physical activity and deteriorating symptoms (Tables 30, 31,32,33,34). From the first month after the intervention, the mean dimension scores of the IG were increased compared to baseline (Tables 30, 31,32,33,34). The multilevel model analysis for the effect of the intervention on the total self-care score for the GR9EHFScBS showed a statistically significant effect of the intervention at all the time points after the intervention ($p < 0.001$) in the overall self-care (Table 35). The Linear Mixed Model results showed a statistically significant effect of the Intervention at all the time points after the intervention ($p < 0.001$) in all the dimensions of the GR9EHFScBS (Tables 36,37,38 respectively).

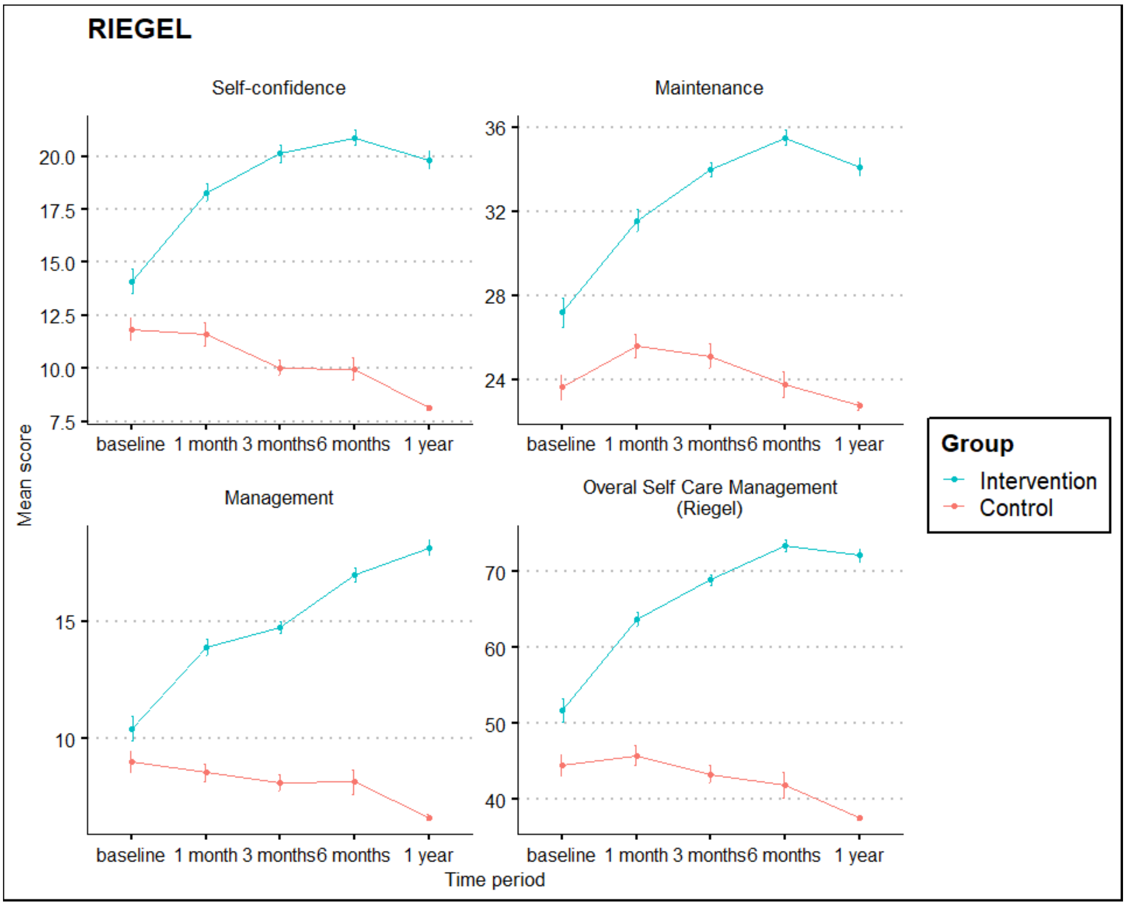

Figure 3: SCHFI means plot

Note: HIGHER scores indicate BETTER self-care

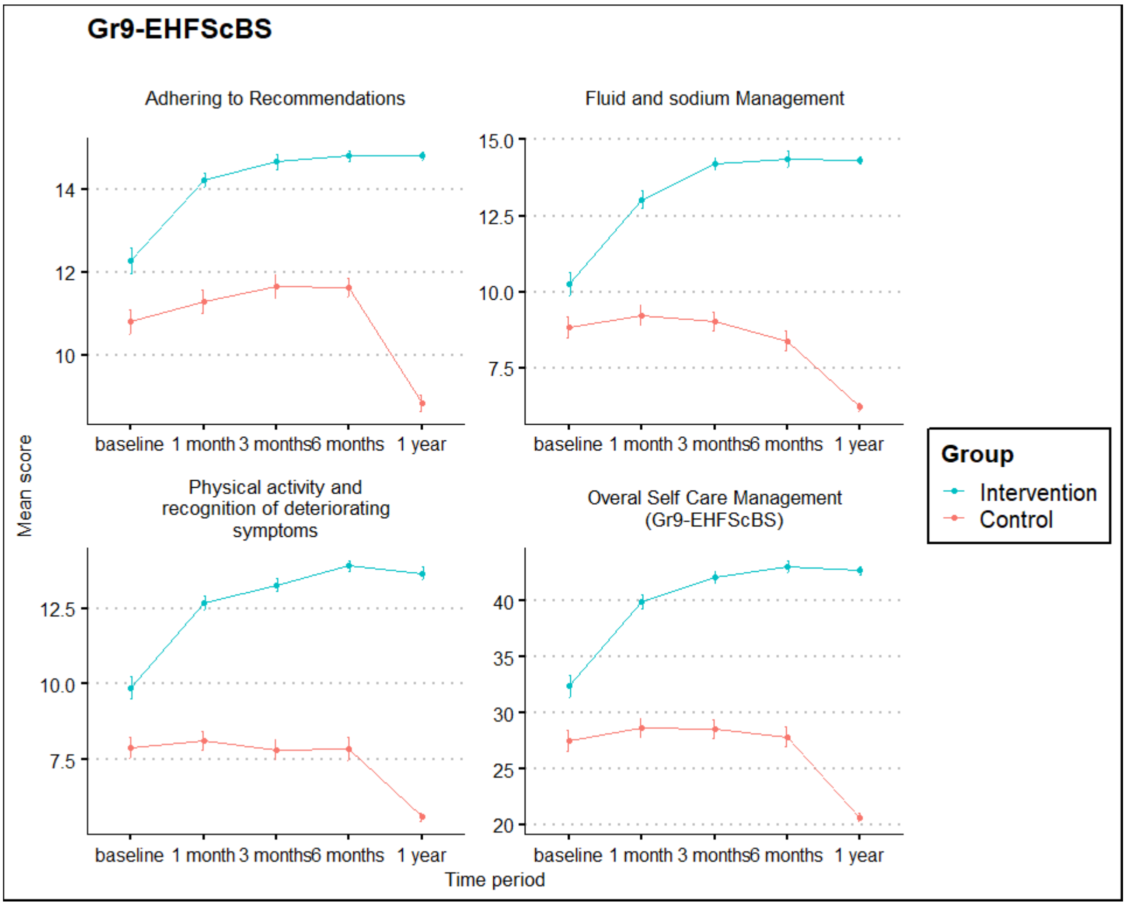

Figure 4: Gr9-EHFScBS means plot

Note: EHFScBS-9 item scores were reverse coded (5 = 1, 4 = 2, 3 = 2, 2 = 1, 1 = 5) so as the dimension scores (totals) had a positive direction - Higher scores indicate better self-care management.

Table 21: SCHFI at baseline

Dimension	**Overall**, N = 121[1]	**Control**, N = 65[1]	**Intervention**, N = 56[1]	**p-value**[2]
Maintenance	25.3 (5.1)	23.6 (4.5)	27.2 (5.1)	<0.001
Management	9.7 (3.8)	9.0 (3.5)	10.4 (4.0)	0.046
Self-confidence	12.9 (4.4)	11.9 (4.2)	14.1 (4.4)	0.005
Overal Self Care Management (Riegel)	47.9 (11.8)	44.5 (10.8)	51.7 (11.9)	<0.001

[1] Mean (SD)

Dimension	**Overall**, N = 121[1]	**Control**, N = 65[1]	**Intervention**, N = 56[1]	**p-value**[2]

[2] Welch Two Sample t-test

Table 22: SCHFI at 1 month

Dimension	**Overall**, N = 120[1]	**Control**, N = 64[1]	**Intervention**, N = 56[1]	**p-value**[2]
Maintenance	28.4 (5.1)	25.6 (4.4)	31.6 (3.8)	<0.001
Management	11.1 (3.9)	8.6 (3.1)	13.9 (2.6)	<0.001
Self-confidence	14.7 (5.0)	11.6 (4.3)	18.3 (3.0)	<0.001
Overal Self Care Management (Riegel)	54.2 (12.9)	45.8 (10.8)	63.8 (7.0)	<0.001

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 23: SCHFI at 3 months

Dimension	**Overall**, N = 113[1]	**Control**, N = 61[1]	**Intervention**, N = 52[1]	**p-value**[2]
Maintenance	29.2 (5.8)	25.1 (4.5)	34.0 (2.4)	<0.001
Management	11.2 (4.0)	8.1 (2.6)	14.8 (1.7)	<0.001
Self-confidence	14.7 (5.8)	10.0 (2.9)	20.1 (2.9)	<0.001
Overal Self Care Management (Riegel)	55.1 (14.9)	43.3 (9.2)	68.9 (5.3)	<0.001

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 24: SCHFI at 6 months

Dimension	**Overall**, N = 107[1]	**Control**, N = 58[1]	**Intervention**, N = 49[1]	**p-value**[2]
Maintenance	29.1 (7.0)	23.8 (4.8)	35.5 (2.5)	<0.001
Management	12.2 (5.5)	8.2 (4.1)	17.0 (2.1)	<0.001
Self-confidence	15.0 (6.4)	10.0 (4.0)	20.9 (2.5)	<0.001
Overal Self Care Management (Riegel)	56.3 (18.5)	41.9 (12.4)	73.4 (5.1)	<0.001

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 25: SCHFI at 1 year

Dimension	**Overall**, N = 100[1]	**Control**, N = 55[1]	**Intervention**, N = 45[1]	**p-value**[2]
Maintenance	27.9 (6.1)	22.7 (1.4)	34.1 (2.9)	<0.001
Management	11.8 (6.0)	6.7 (0.9)	18.1 (2.2)	<0.001
Self-confidence	13.4 (6.1)	8.1 (0.8)	19.8 (2.6)	<0.001
Overal Self Care Management (Riegel)	53.1 (17.8)	37.5 (2.0)	72.1 (5.9)	<0.001

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 26: Linear Mixed Model Effect (LMME) for the effect of the intervention on the overall self -care (SCHFI)

Effect	**Beta**	**95% CI**[1]	**p-value**
Group			
Control	—	—	
Intervention	7.3	3.9, 11	<0.001
Time point			
baseline	—	—	
1 month	0.84	-1.8, 3.5	0.5
3 months	-0.54	-3.3, 2.2	0.7
6 months	-2.0	-5.0, 0.91	0.2
1 year	-6.0	-8.7, -3.2	<0.001
Age	-0.02	-0.16, 0.12	0.8
Sex			
Male	—	—	
Female	0.13	-2.5, 2.8	>0.9
Ejection Fraction(EF)	0.01	-0.13, 0.16	0.8
HbA1c	0.04	-1.7, 1.8	>0.9
NYHA			
II	—	—	
III	-0.18	-3.0, 2.7	>0.9
IV	-0.03	-3.8, 3.7	>0.9
Alcoholic	4.1	-3.5, 12	0.3

Effect	**Beta**	**95% CI[1]**	**p-value**
Obesity	0.10	-3.1, 3.3	>0.9
Smoking	1.9	-0.92, 4.8	0.2
Hyperlipidemia	-0.18	-2.6, 2.2	0.9
Hypertension	-2.2	-5.2, 0.73	0.14
Arrythmias	-0.57	-3.0, 1.8	0.6
Valvular disease	1.4	-2.5, 5.2	0.5
Coronary artery	-4.8	-7.7, -2.0	0.001
Group * Time point			
Intervention * 1 month	12	7.8, 16	<0.001
Intervention * 3 months	18	14, 22	<0.001
Intervention * 6 months	24	20, 28	<0.001
Intervention * 1 year	27	22, 31	<0.001

[1] CI = Confidence Interval

Table 27: Linear Mixed Model Effect (LMME) for the effect of the Intervention on the maintenance (SCHFI)

Effect	**Beta**	**95% CI**[1]	**p-value**
Group			
Control	—	—	
Intervention	3.7	2.2, 5.2	<0.001
Time point			
baseline	—	—	
1 month	1.8	0.60, 3.0	0.004
3 months	1.8	0.56, 3.1	0.005
6 months	0.47	-0.88, 1.8	0.5
1 year	-0.57	-1.8, 0.68	0.4
Age	0.02	-0.04, 0.08	0.6
Sex			
Male	—	—	
Female	0.32	-0.81, 1.5	0.6
Ejection Fraction(EF)	0.02	-0.05, 0.08	0.6
HbA1c	-0.06	-0.82, 0.70	0.9
NYHA			
II	—	—	
III	-0.34	-1.6, 0.88	0.6
IV	0.15	-1.5, 1.8	0.9
Alcoholic	0.40	-2.9, 3.7	0.8

Effect	**Beta**	**95% CI[1]**	**p-value**
Obesity	-0.11	-1.5, 1.3	0.9
Smoking	0.78	-0.44, 2.0	0.2
Hyperlipidemia	0.32	-0.72, 1.4	0.5
Hypertension	-0.90	-2.2, 0.38	0.2
Arrythmias	-0.11	-1.1, 0.92	0.8
Valvular disease	0.49	-1.2, 2.1	0.6
Coronary artery	-1.7	-3.0, -0.49	0.007
Group * Time point			
Intervention * 1 month	2.6	0.81, 4.4	0.005
Intervention * 3 months	5.2	3.4, 7.1	<0.001
Intervention * 6 months	8.1	6.2, 10	<0.001
Intervention * 1 year	7.5	5.7, 9.4	<0.001
[1]CI = Confidence Interval			

Table 28: Linear Mixed Model Effect (LMME) for the effect of the intervention on the management (SCHFI)

Effect	Beta	95% CI[1]	p-value
Group			
Control	—	—	
Intervention	1.3	0.19, 2.4	0.022
Time point			
baseline	—	—	
1 month	-0.53	-1.4, 0.35	0.2
3 months	-0.70	-1.6, 0.21	0.13
6 months	-0.74	-1.7, 0.22	0.13
1 year	-2.1	-3.0, -1.2	<0.001
Age	-0.02	-0.06, 0.03	0.5
Sex			
Male	—	—	
Female	-0.24	-1.1, 0.63	0.6
LV ejection fraction)	0.00	-0.05, 0.05	>0.9
HbA1c	0.06	-0.52, 0.64	0.8
NYHA			
II	—	—	
III	0.16	-0.78, 1.1	0.7
IV	0.13	-1.1, 1.4	0.8

Effect	**Beta**	**95% CI[1]**	**p-value**
Alcoholic	0.87	-1.7, 3.4	0.5
Obesity	-0.04	-1.1, 1.0	>0.9
Smoking	0.42	-0.52, 1.4	0.4
Hyperlipidemia	-0.14	-0.94, 0.67	0.7
Hypertension	-0.74	-1.7, 0.24	0.14
Arrythmias	-0.18	-0.98, 0.62	0.7
Valvular disease	0.47	-0.81, 1.7	0.5
Coronary artery	-1.5	-2.4, -0.50	0.003
Group * Time point			
Intervention * 1 month	4.1	2.8, 5.4	<0.001
Intervention * 3 months	5.1	3.8, 6.4	<0.001
Intervention * 6 months	7.5	6.1, 8.9	<0.001
Intervention * 1 year	10	8.7, 11	<0.001

[1] CI = Confidence Interval

Table 29: Linear Mixed Model Effect (LMME) for the effect of the Intervention on the self-confidence (SCHFI)

Effect	**Beta**	**95% CI**[1]	**p-value**
Group			
Control	—	—	
Intervention	2.3	1.0, 3.5	<0.001
Time point			
baseline	—	—	
1 month	-0.44	-1.5, 0.62	0.4
3 months	-1.7	-2.8, -0.59	0.003
6 months	-1.7	-2.9, -0.57	0.004
1 year	-3.4	-4.5, -2.3	<0.001
Age	-0.02	-0.07, 0.02	0.4
Sex			
Male	—	—	
Female	0.05	-0.83, 0.93	>0.9
Ejection Fraction(EF)	0.00	-0.05, 0.05	>0.9
HbA1c	0.04	-0.57, 0.65	0.9
NYHA			
II	—	—	
III	0.00	-0.95, 0.95	>0.9
IV	-0.33	-1.6, 0.94	0.6

Effect	**Beta**	**95% CI[1]**	**p-value**
Alcoholic	2.7	0.16, 5.3	0.038
Obesity	0.27	-0.82, 1.3	0.6
Smoking	0.70	-0.25, 1.7	0.15
Hyperlipidemia	-0.37	-1.2, 0.44	0.4
Hypertension	-0.58	-1.6, 0.42	0.2
Arrythmias	-0.27	-1.1, 0.54	0.5
Valvular disease	0.38	-0.91, 1.7	0.6
Coronary artery	-1.6	-2.6, -0.65	0.001
Group * Time point			
Intervention * 1 month	4.9	3.4, 6.5	<0.001
Intervention * 3 months	7.8	6.2, 9.4	<0.001
Intervention * 6 months	8.5	6.9, 10	<0.001
Intervention * 1 year	9.1	7.5, 11	<0.001

[1] CI = Confidence Interval

Table 30: Gr9EHFScBS at baseline

Dimension	**Overall**, N = 121[1]	**Control**, N = 65[1]	**Intervention**, N = 56[1]	**p-value**[2]
Adhering to Recommendations	11.5 (2.4)	10.8 (2.3)	12.3 (2.3)	<0.001
Fluid and sodium Management	9.5 (2.9)	8.8 (2.8)	10.2 (3.0)	0.008
Physical activity and recognition of deteriorating symptoms	8.8 (2.9)	7.9 (2.7)	9.9 (2.8)	<0.001
Overal Self Care Management (EHFScBS)	29.8 (7.8)	27.5 (7.4)	32.4 (7.4)	<0.001

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 31: Gr9EHFScBS at 1 month

Dimension	**Overall**, N = 120[1]	**Control**, N = 64[1]	**Intervention**, N = 56[1]	**p-value**[2]
Adhering to Recommendations	12.7 (2.4)	11.3 (2.3)	14.2 (1.4)	<0.001
Fluid and sodium Management	11.0 (3.1)	9.2 (2.7)	13.0 (2.1)	<0.001
Physical activity and recognition of deteriorating symptoms	10.2 (3.1)	8.1 (2.5)	12.7 (1.7)	<0.001
Overal Self Care Management (Gr9-EHFScBS)	33.9 (8.1)	28.6 (6.8)	39.9 (4.5)	<0.001

[1] Mean (SD)

Dimension	**Overall**, N = 120[1]	**Control**, N = 64[1]	**Intervention**, N = 56[1]	**p-value**[2]

[2]Welch Two Sample t-test

Table 32: Gr9EHFScBS at 3 months

Dimension	**Overall**, N = 113[1]	**Control**, N = 61[1]	**Intervention**, N = 52[1]	**p-value**[2]
Adhering to Recommendations	13.0 (2.4)	11.7 (2.1)	14.7 (1.3)	<0.001
Fluid and sodium Management	11.4 (3.3)	9.0 (2.4)	14.2 (1.5)	<0.001
Physical activity and recognition of deteriorating symptoms	10.3 (3.4)	7.8 (2.5)	13.3 (1.5)	<0.001
Overal Self Care Management (EHFScBS)	34.8 (8.7)	28.5 (6.5)	42.1 (4.0)	<0.001

[1]Mean (SD)

[2]Welch Two Sample t-test

Table 33: Gr9HFScBS at 6 months

Dimension	**Overall**, N = 107[1]	**Control**, N = 58[1]	**Intervention**, N = 49[1]	**p-value**[2]
Adhering to Recommendations	13.1 (2.2)	11.6 (1.8)	14.8 (0.9)	<0.001
Fluid and sodium Management	11.1 (3.7)	8.4 (2.5)	14.4 (1.9)	<0.001
Physical activity and recognition of deteriorating symptoms	10.6 (3.7)	7.9 (2.8)	13.9 (1.2)	<0.001

Dimension	**Overall**, N = 107[1]	**Control**, N = 58[1]	**Intervention**, N = 49[1]	**p-value**[2]
Overal Self Care Management (EHFScBS)	34.8 (9.4)	27.9 (6.7)	43.1 (3.8)	<0.001

[1]Mean (SD)

[2]Welch Two Sample t-test

Table 34: Gr9EHFScBS at 1 year

Dimension	**Overall**, N = 100[1]	**Control**, N = 55[1]	**Intervention**, N = 45[1]	**p-value**[2]
Adhering to Recommendations	11.5 (3.2)	8.8 (1.4)	14.8 (0.7)	<0.001
Fluid and sodium Management	9.9 (4.1)	6.2 (1.0)	14.3 (0.8)	<0.001
Physical activity and recognition of deteriorating symptoms	9.2 (4.2)	5.6 (1.0)	13.6 (1.4)	<0.001
Overal Self Care Management (Gr9-EHFScBS)	30.6 (11.3)	20.7 (2.6)	42.8 (2.4)	<0.001

[1]Mean (SD)

[2]Welch Two Sample t-test

Table 35: LMME for the effect of the Intervention on the overall self -care (GR9EHFScBS)

Effect	**Beta**	**95% CI**[1]	**p-value**
Group			
Control	—	—	
Intervention	5.1	2.9, 7.3	<0.001
Time point			
baseline	—	—	
1 month	0.92	-0.74, 2.6	0.3
3 months	1.5	-0.26, 3.2	0.095
6 months	0.88	-0.95, 2.7	0.3
1 year	-6.2	-7.9, -4.4	<0.001
Age	0.00	-0.09, 0.09	>0.9
Sex			
Male	—	—	
Female	0.13	-1.6, 1.9	0.9
Ejection Fraction (EF)	-0.02	-0.12, 0.08	0.7
HbA1c	0.24	-0.90, 1.4	0.7
NYHA			
II	—	—	
III	-0.28	-2.2, 1.6	0.8
IV	-1.4	-3.9, 1.1	0.3
Alcoholic	3.3	-1.7, 8.4	0.2

Effect	**Beta**	**95% CI[1]**	**p-value**
Obesity	0.84	-1.3, 3.0	0.4
Smoking	0.92	-0.96, 2.8	0.3
Hyperlipidemia	1.0	-0.59, 2.6	0.2
Hypertension	-1.3	-3.3, 0.66	0.2
Arrythmias	-1.0	-2.6, 0.56	0.2
Valvular disease	1.3	-1.2, 3.9	0.3
Coronary artery	-3.5	-5.4, -1.6	<0.001
Group * Time point			
Intervention * 1 month	6.4	3.9, 8.8	<0.001
Intervention * 3 months	8.4	5.8, 11	<0.001
Intervention * 6 months	9.9	7.3, 12	<0.001
Intervention * 1 year	16	14, 19	<0.001

[1] CI = Confidence Interval

Table 36: Linear Mixed Model Effect (LMME) for the effect of the intervention on the adhering to recommendations (Gr9EHFScBS*)*

Effect	**Beta**	**95% CI**[1]	**p-value**
Group			
Control	—	—	
Intervention	1.6	0.88, 2.2	<0.001
Time point			
baseline	—	—	
1 month	0.38	-0.17, 0.94	0.2
3 months	0.98	0.40, 1.6	<0.001
6 months	0.98	0.37, 1.6	0.002
1 year	-1.8	-2.4, -1.2	<0.001
Age	0.00	-0.02, 0.03	>0.9
Sex			
Male	—	—	
Female	0.20	-0.29, 0.69	0.4
Ejection Fraction (EF)	-0.01	-0.04, 0.02	0.4
HbA1c	0.03	-0.30, 0.37	0.8
NYHA			
II	—	—	
III	0.03	-0.49, 0.56	>0.9
IV	-0.15	-0.86, 0.55	0.7

Effect	**Beta**	**95% CI[1]**	**p-value**
Alcoholic	0.83	-0.59, 2.3	0.2
Obesity	0.27	-0.33, 0.87	0.4
Smoking	0.35	-0.18, 0.87	0.2
Hyperlipidemia	0.45	0.00, 0.90	0.050
Hypertension	-0.33	-0.88, 0.23	0.2
Arrythmias	-0.23	-0.68, 0.22	0.3
Valvular disease	0.75	0.03, 1.5	0.040
Coronary artery	-1.2	-1.7, -0.64	<0.001
Group * Time point			
Intervention * 1 month	1.5	0.71, 2.3	<0.001
Intervention * 3 months	1.4	0.59, 2.3	<0.001
Intervention * 6 months	1.6	0.69, 2.4	<0.001
Intervention * 1 year	4.3	3.5, 5.1	<0.001

[1] CI = Confidence Interval

Table 37: Linear Mixed Model Effect (LMME) for the effect of the intervention on the fluid and sodium management (Gr9EHFScBS)

Effect	**Beta**	**95% CI**^{1}	**p-value**
Group			
Control	—	—	
Intervention	1.5	0.67, 2.4	<0.001
Time point			
baseline	—	—	
1 month	0.37	-0.28, 1.0	0.3
3 months	0.40	-0.29, 1.1	0.3
6 months	-0.25	-0.97, 0.48	0.5
1 year	-2.4	-3.0, -1.7	<0.001
Age	0.00	-0.03, 0.04	0.9
Sex			
Male	—	—	
Female	-0.10	-0.79, 0.60	0.8
Ejection Fraction (EF)	0.01	-0.03, 0.04	0.8
HbA1c	0.10	-0.35, 0.55	0.7
NYHA			
II	—	—	
III	-0.10	-0.85, 0.65	0.8
IV	-0.41	-1.4, 0.58	0.4
Alcoholic	0.71	-1.3, 2.7	0.5

Effect	**Beta**	**95% CI[1]**	**p-value**
Obesity	0.18	-0.67, 1.0	0.7
Smoking	0.32	-0.43, 1.1	0.4
Hyperlipidemia	0.32	-0.32, 0.96	0.3
Hypertension	-0.44	-1.2, 0.35	0.3
Arrythmias	-0.40	-1.0, 0.24	0.2
Valvular disease	0.41	-0.61, 1.4	0.4
Coronary artery	-1.1	-1.8, -0.31	0.006
Group * Time point			
Intervention * 1 month	2.3	1.3, 3.2	<0.001
Intervention * 3 months	3.6	2.6, 4.6	<0.001
Intervention * 6 months	4.5	3.5, 5.5	<0.001
Intervention * 1 year	6.4	5.4, 7.4	<0.001

[1] CI = Confidence Interval

Table 38: Linear Mixed Model Effect (LMME) for the effect of the intervention on the physical activity and recognition of deteriorating symptoms (Gr9EHFScBS)

Effect	**Beta**	**95% CI**[1]	**p-value**
Group			
Control	—	—	
Intervention	2.0	1.2, 2.8	<0.001
Time point			
baseline	—	—	
1 month	0.17	-0.47, 0.81	0.6
3 months	0.08	-0.59, 0.75	0.8
6 months	0.15	-0.56, 0.86	0.7
1 year	-2.0	-2.7, -1.4	<0.001
Age	0.00	-0.04, 0.03	>0.9
Sex			
Male	—	—	
Female	0.04	-0.62, 0.69	>0.9
Ejection Fraction (EF)	-0.01	-0.05, 0.02	0.5

HbA1c	0.10	-0.33, 0.53	0.7
NYHA			
II	—	—	
III	-0.21	-0.92, 0.49	0.5
IV	-0.79	-1.7, 0.15	0.10
Alcoholic	1.7	-0.19, 3.6	0.078
Obesity	0.39	-0.41, 1.2	0.3
Smoking	0.26	-0.45, 0.97	0.5
Hyperlipidemia	0.23	-0.37, 0.84	0.4
Hypertension	-0.56	-1.3, 0.18	0.14
Arrythmias	-0.38	-0.98, 0.22	0.2
Valvular disease	0.16	-0.80, 1.1	0.7
Coronary artery	-1.3	-2.0, -0.54	<0.001
Group * Time point			
Intervention * 1 month	2.6	1.7, 3.6	<0.001
Intervention * 3 months	3.4	2.4, 4.3	<0.001
Intervention * 6 months	3.9	2.9, 4.9	<0.001

Intervention * 1 year	5.8	4.8, 6.7	<0.001
[1]CI = Confidence Interval			

9.6 Anxiety and Depression

The anxiety and depressive symptoms were measured using the HADS questionnaire which has the dimensions of anxiety and depression. Graph in figure 5 shows the average scores across time, for the dimensions of HADS. At baseline, in one month, in three months, six months and in one year, the IG had lower emotional distress compared to the CG (Tables 39,40, 41,42,43 respectively). At one year after the intervention $p < 0.001$ in all the dimensions of the HADS. The multilevel model for the effect of the intervention on the HADS in the overall emotional distress, showed no statistically significant effect of the intervention at any of the time points after the intervention ($p > 0.05$) but there was a declining trend especially between three months and one year after the intervention (Table 44). Also, the Linear Mixed Model results, showed no statistically significant effect of the intervention at any of the time points after the intervention ($p > 0.05$) at the dimension of anxiety and at the dimension of depression ($p= 0.004$) (Tables 45,46 respectively) but a declining trend in the two dimensions was observed between 3 months to one year after the intervention.

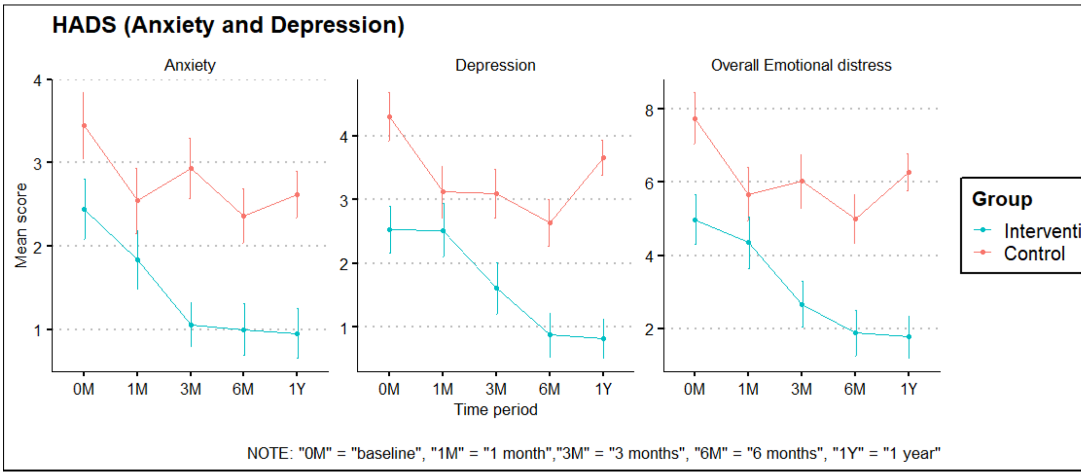

Figure 5: HADS (Anxiety and Depression)

Note: HIGHER scores indicate HIGHER emotional distress

Table 39: HADS (Anxiety and Depression) at baseline

Dimension	**Overall**, N = 121[1]	**Control**, N = 65[1]	**Intervention**, N = 56[1]	**p-value**[2]
Anxiety	3.0 (3.0)	3.4 (3.1)	2.4 (2.7)	0.064
Depression	3.5 (3.0)	4.3 (3.0)	2.5 (2.7)	0.001
Overall Emotional distress	6.4 (5.5)	7.7 (5.6)	5.0 (5.1)	0.005

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 40*:* HADS (Anxiety and Depression) at 1 month

Dimension	**Overall**, N = 120[1]	**Control**, N = 64[1]	**Intervention**, N = 56[1]	**p-value**[2]
Anxiety	2.2 (2.9)	2.5 (3.1)	1.8 (2.6)	0.2
Depression	2.8 (3.2)	3.1 (3.2)	2.5 (3.1)	0.3
Overall Emotional distress	5.1 (5.6)	5.7 (5.9)	4.4 (5.3)	0.2

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 41: HADS (Anxiety and Depression) at 3 months

Dimension	**Overall**, N = 113[1]	**Control**, N = 61[1]	**Intervention**, N = 52[1]	**p-value**[2]
Anxiety	2.1 (2.6)	2.9 (2.9)	1.1 (1.9)	<0.001
Depression	2.4 (3.0)	3.1 (3.0)	1.6 (2.9)	0.009
Overall Emotional distress	4.5 (5.5)	6.0 (5.7)	2.7 (4.5)	<0.001

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 42: HADS (Anxiety and Depression) at 6 months

Dimension	**Overall**, N = 107[1]	**Control**, N = 58[1]	**Intervention**, N = 49[1]	**p-value**[2]
Anxiety	1.7 (2.4)	2.4 (2.5)	1.0 (2.2)	0.003
Depression	1.8 (2.7)	2.6 (2.8)	0.9 (2.4)	<0.001
Overall Emotional distress	3.6 (5.0)	5.0 (5.1)	1.9 (4.5)	0.001

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 43: HADS (Anxiety and Depression) at 1 year

Dimension	**Overall**, N = 100[1]	**Control**, N = 55[1]	**Intervention**, N = 45[1]	**p-value**[2]
Anxiety	1.9 (2.2)	2.6 (2.0)	1.0 (2.0)	<0.001
Depression	2.4 (2.5)	3.7 (2.0)	0.8 (2.0)	<0.001
Overall Emotional distress	4.2 (4.4)	6.3 (3.7)	1.8 (3.9)	<0.001

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 44: Linear Mixed Model Effect (LMME) for the effect of the intervention on the overall emotional distress (HADS)

Effect	**Beta**	**95% CI[1]**	**p-value**
Group			
Control	—	—	
Intervention	-2.5	-4.4, -0.61	0.010
Time point			
baseline	—	—	
1 month	-2.2	-3.7, -0.69	0.004
3 months	-2.4	-4.0, -0.81	0.003
6 months	-1.9	-3.5, -0.21	0.028
1 year	-1.4	-3.0, 0.13	0.072
Age	-0.04	-0.11, 0.04	0.3
Sex			
Male	—	—	
Female	0.62	-0.80, 2.0	0.4
Ejection Fraction (EF)	-0.03	-0.11, 0.05	0.5
HbA1c	0.80	-0.15, 1.7	0.10
NYHA			
II	—	—	
III	1.2	-0.36, 2.7	0.13

IV	1.7	-0.31, 3.8	0.10
Alcoholic	-3.0	-7.1, 1.1	0.2
Obesity	-1.8	-3.6, -0.10	0.038
Smoking	0.11	-1.4, 1.6	0.9
Hyperlipidemia	-0.68	-2.0, 0.62	0.3
Hypertension	2.4	0.82, 4.0	0.003
Arrythmias	0.36	-0.93, 1.7	0.6
Valvular disease	-0.37	-2.4, 1.7	0.7
Coronary artery	0.04	-1.5, 1.6	>0.9
Group * Time point			
Intervention * 1 month	1.3	-0.96, 3.5	0.3
Intervention * 3 months	0.01	-2.3, 2.3	>0.9
Intervention * 6 months	-1.1	-3.5, 1.2	0.3
Intervention * 1 year	-1.3	-3.6, 1.0	0.3

[1]CI = Confidence Interval

Table 33: Linear Mixed Model Effect (LMME) for the effect of the Intervention on the anxiety (HADS)

Effect	**Beta**	**95% CI**[1]	**p-value**
Group			
Control	—	—	
Intervention	-0.94	-1.9, 0.02	0.054
Time point			
baseline	—	—	
1 month	-1.0	-1.8, -0.22	0.013
3 months	-0.84	-1.7, -0.02	0.045
6 months	-0.63	-1.5, 0.24	0.2
1 year	-0.83	-1.6, -0.01	0.046
Age	-0.02	-0.06, 0.01	0.2
Sex			
Male	—	—	
Female	0.29	-0.40, 0.99	0.4

Ejection Fraction (EF)	-0.02	-0.06, 0.02	0.3
HbA1c	0.31	-0.16, 0.79	0.2
NYHA			
II	—	—	
III	0.62	-0.12, 1.4	0.10
IV	0.67	-0.33, 1.7	0.2
Alcoholic	-1.1	-3.1, 0.91	0.3
Obesity	-0.79	-1.6, 0.05	0.066
Smoking	0.02	-0.73, 0.76	>0.9
Hyperlipidemia	-0.25	-0.89, 0.38	0.4
Hypertension	1.1	0.33, 1.9	0.006
Arrythmias	0.14	-0.49, 0.77	0.7
Valvular disease	-0.02	-1.0, 0.99	>0.9
Coronary artery	0.06	-0.70, 0.81	0.9
Group * Time point			
Intervention * 1 month	0.18	-0.99, 1.3	0.8
Intervention * 3 months	-0.65	-1.8, 0.55	0.3

Intervention * 6 months	-0.84	-2.1, 0.38	0.2
Intervention * 1 year	-0.50	-1.7, 0.71	0.4
^{1}CI = Confidence Interval			

Table 46: Linear Mixed Model Effect (LMME) for the effect of the Intervention on the depression (HADS)

Effect	**Beta**	**95% CI^1**	**p-value**
Group			
Control	—	—	
Intervention	-1.6	-2.6, -0.50	0.004
Time point			
baseline	—	—	
1 month	-1.2	-2.0, -0.36	0.005
3 months	-1.5	-2.4, -0.66	<0.001
6 months	-1.2	-2.2, -0.32	0.008
1 year	-0.60	-1.5, 0.27	0.2
Age	-0.02	-0.06, 0.03	0.4
Sex			
Male	—	—	
Female	0.32	-0.48, 1.1	0.4

Ejection Fraction (EF)	-0.01	-0.05, 0.04	0.8
HbA1c	0.47	-0.07, 1.0	0.085
NYHA			
II	—	—	
III	0.54	-0.32, 1.4	0.2
IV	1.1	-0.09, 2.2	0.070
Alcoholic	-1.9	-4.2, 0.48	0.12
Obesity	-1.0	-2.0, -0.05	0.039
Smoking	0.10	-0.77, 0.96	0.8
Hyperlipidemia	-0.42	-1.2, 0.32	0.3
Hypertension	1.3	0.40, 2.2	0.005
Arrythmias	0.23	-0.51, 0.96	0.5
Valvular disease	-0.35	-1.5, 0.82	0.6
Coronary artery	-0.02	-0.90, 0.85	>0.9
Group * Time point			
Intervention * 1 month	1.1	-0.14, 2.3	0.082
Intervention * 3 months	0.64	-0.63, 1.9	0.3
Intervention * 6 months	-0.31	-1.6,1.0	0.6
Intervention * 1 year	-0.81	-2.1,0.48	0.2

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[1] CI = Confidence Interval

9.7 Physical Activity

The IPAQ questionnaire measures the physical activity through a multiple of your estimated resting energy expenditure (MET minutes/ week: MET minutes represent the amount of energy expended carrying out physical activity). Figure 6 shows the average scores across time, for the Physical Activity (IPAQ) dimensions. At baseline, the IG had higher overall physical activity compared to CG ($p=0.002$). No statistically significant difference between the two groups was found at baseline with respect to the specific IPAQ dimensions (Table 47). No statistically significant difference was found between IG and CG a month after the intervention ($p=0.2$), in the overall physical activity (Table 48) but there was an icreases trend in the IG ater the first month to six months compared with the CG. At three months, six months and one year after the intervention, the IG showed more overall physical activity compared to the CG ($p<0.001$), and specifically higher walking ($p < 0.001$) and moderate exercise ($p < 0.001$) (Tables 49,50,51 respectively).

The multilevel model for the effect of the intervention on physical activity did not show a statistically significant effect of the intervention at any time point for the overall physical activity (Table 52) but there was an icreases trend in the IG compared with the CG between a month to six months after the intervention. Linear Mixed Model results for the dimension of walking showed a statistically significant effect of the Intervention at the 1st month after the intervention ($p< 0.001$) and at 3 months ($p < 0.001$) (Table 53). In the dimension of moderate exercise Linear Mixed Model results did not showed any statistically significant effect of the intervention at any time point after the intervention ($p > 0.05$) (Table 54) but an icrease trend was observed especially between a month to six months after the intervention. The Linear Mixed Model Effect for the effect of the intervention on the vigorous exercise of the IPAQ is shown in table 55.

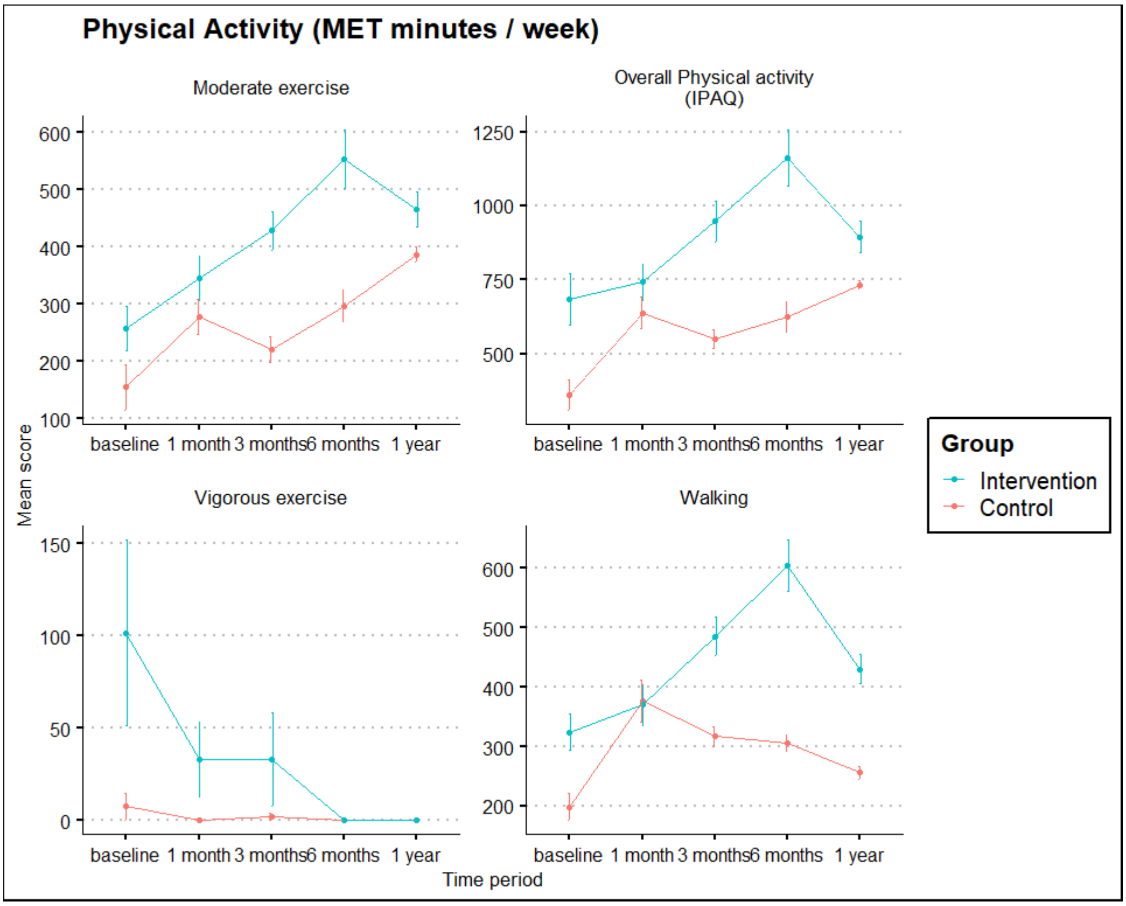

Figure 6: Physical activity (IPAQ) means plot

Table 34: Physical activity at baseline (MET minutes / week)

Dimension	**Overall**, N = 121[1]	**Control**, N = 65[1]	**Intervention**, N = 56[1]	**p-value**[2]
Walking	257.0 (212.9)	199.0 (181.8)	324.5 (227.6)	0.001
Moderate exercise	202.3 (312.8)	154.8 (322.6)	257.5 (294.3)	0.070
Vigorous exercise	50.9 (263.2)	7.4 (59.5)	101.4 (377.0)	0.070
Overall Physical activity (IPAQ)	510.3 (553.3)	361.1 (409.2)	683.4 (645.2)	0.002

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 48: Physical Activity at 1 month (MET minutes / week)

Dimension	**Overall**, N = 120[1]	**Control**, N = 64[1]	**Intervention**, N = 56[1]	**p-value**[2]
Walking	373.6 (267.5)	376.7 (286.1)	369.8 (245.0)	0.9
Moderate exercise	309.9 (240.4)	278.0 (218.7)	345.2 (260.3)	0.2
Vigorous exercise	15.3 (103.5)	0.0 (0.0)	32.7 (150.5)	0.11
Overall Physical activity (IPAQ)	687.4 (402.6)	637.9 (385.5)	742.2 (418.0)	0.2

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 49: Physical Activity at 3 months (MET minutes / week)

Dimension	**Overall**, N = 113[1]	**Control**, N = 61[1]	**Intervention**, N = 52[1]	**p-value**[2]
Walking	394.5 (202.2)	317.4 (129.6)	484.8 (233.7)	<0.001
Moderate exercise	328.6 (229.6)	220.8 (152.0)	428.1 (245.0)	<0.001
Vigorous exercise	16.2 (122.7)	2.0 (15.5)	32.9 (179.7)	0.2
Overall Physical activity (IPAQ)	754.6 (434.9)	550.3 (230.3)	946.9 (493.1)	<0.001

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 35: Physical activity at 6 months (MET minutes / week)

Dimension	**Overall**, N = 107[1]	**Control**, N = 58[1]	**Intervention**, N = 49[1]	**p-value**[2]
Walking	444.9 (265.2)	305.9 (107.9)	603.8 (301.2)	<0.001
Moderate exercise	470.3 (322.2)	296.9 (134.8)	553.3 (352.6)	<0.001
Vigorous exercise	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	
Overall Physical activity (IPAQ)	985.5 (597.8)	624.7 (242.0)	1,162.0 (641.2)	<0.001

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 51: Physical Activity at 1 year (MET minutes / week)

Dimension	**Overall**, N = 100[1]	**Control**, N = 55[1]	**Intervention**, N = 45[1]	**p-value**[2]
Walking	334.6 (151.1)	256.0 (82.6)	430.5 (160.9)	<0.001
Moderate exercise	456.1 (191.0)	386.7 (32.7)	465.8 (201.9)	0.023
Vigorous exercise	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	
Overall Physical activity (IPAQ)	875.0 (335.5)	733.2 (32.7)	894.8 (353.9)	0.006

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 52: Linear Mixed Model Effect (LMME) for the effect of the Intervention on the overall physical activity (IPAQ)

Effect	**Beta**	**95% CI**[1]	**p-value**
Group			
Control	—	—	
Intervention	312	135, 489	<0.001
Time point			
baseline	—	—	
1 month	250	87, 413	0.003
3 months	195	23, 367	0.027
6 months	271	22, 519	0.033
1 year	333	-44, 710	0.083
Age	-5.7	-12, 0.99	0.094
Sex			
Male	—	—	
Female	11	-123, 146	0.9
Ejection Fraction (EF)	-0.66	-7.9, 6.6	0.9
HbA1c	-22	-114, 69	0.6
NYHA			
II	—	—	
III	-114	-253, 25	0.11
IV	-202	-394, -9.3	0.040

Effect	**Beta**	**95% CI[1]**	**p-value**
Alcoholic	24	-338, 386	0.9
Obesity	63	-98, 225	0.4
Smoking	-16	-154, 122	0.8
Hyperlipidemia	-43	-164, 78	0.5
Hypertension	10	-135, 155	0.9
Arrythmias	-64	-183, 56	0.3
Valvular disease	-57	-256, 142	0.6
Coronary artery	122	-21, 264	0.093
Group * Time point			
Intervention * 1 month	-199	-439, 41	0.10
Intervention * 3 months	71	-169, 311	0.6
Intervention * 6 months	207	-92, 506	0.2
Intervention * 1 year	-151	-565, 262	0.5

[1] CI = Confidence Interval

Table 53: Linear Mixed Model Effect (LMME) for the effect of the Intervention on the walking (IPAQ)

Effect	Beta	95% CI[1]	p-value
Group			
Control	—	—	
Intervention	107	26, 188	0.010
Time point			
baseline	—	—	
1 month	180	115, 246	<0.001
3 months	126	58, 194	<0.001
6 months	98	25, 170	0.008
1 year	48	-19, 115	0.2
Age	-1.3	-4.5, 1.9	0.4
Sex			
Male	—	—	
Female	-10	-71, 50	0.7
Ejection Fraction(EF)	-1.0	-4.4, 2.3	0.5
HbA1c	-27	-68, 14	0.2
NYHA			
II	—	—	
III	-65	-131, -0.39	0.049
IV	-103	-190, -16	0.021

Effect	**Beta**	**95% CI**[1]	**p-value**
Alcoholic	35	-144, 213	0.7
Obesity	10	-64, 85	0.8
Smoking	-28	-93, 37	0.4
Hyperlipidemia	4.6	-51, 60	0.9
Hypertension	-8.3	-77, 60	0.8
Arrythmias	-17	-73, 38	0.5
Valvular disease	-25	-114, 64	0.6
Coronary artery	84	18, 150	0.014
Group * Time point			
Intervention * 1 month	-140	-238, -41	0.006
Intervention * 3 months	33	-66, 133	0.5
Intervention * 6 months	177	75, 279	<0.001
Intervention * 1 year	39	-61, 139	0.4

[1] CI = Confidence Interval

Table 54: Linear Mixed Model Effect (LMME) for the effect of the intervention on the moderate exercise (IPAQ)

Effect	**Beta**	**95% CI**[1]	**p-value**
Group			
Control	—	—	
Intervention	101	0.15, 201	0.050
Time point			
baseline	—	—	
1 month	99	5.3, 193	0.038
3 months	69	-31, 168	0.2
6 months	134	-8.6, 277	0.065
1 year	206	-10, 423	0.062
Age	-4.2	-7.9, -0.44	0.029
Sex			
Male	—	—	
Female	42	-34, 117	0.3
Ejection Fraction (EF)	-1.1	-5.2, 2.9	0.6
HbA1c	-9.6	-61, 42	0.7
NYHA			
II	—	—	
III	-51	-129, 27	0.2
IV	-102	-210, 5.4	0.063

Effect	**Beta**	**95% CI**[1]	**p-value**
Alcoholic	-3.8	-206, 199	>0.9
Obesity	-11	-101, 79	0.8
Smoking	-4.3	-82, 73	>0.9
Hyperlipidemia	-22	-90, 45	0.5
Hypertension	20	-61, 101	0.6
Arrythmias	-21	-88, 46	0.5
Valvular disease	-24	-136, 88	0.7
Coronary artery	14	-65, 94	0.7
Group * Time point			
Intervention * 1 month	-11	-149, 127	0.9
Intervention * 3 months	104	-34, 242	0.14
Intervention * 6 months	160	-12, 331	0.068
Intervention * 1 year	-12	-250, 226	>0.9

[1] CI = Confidence Interval

Table 55: Linear Mixed Model Effect (LMME) for the effect of the intervention on the vigorous exercise (IPAQ)

Effect	**Beta**	**95% CI**[1]	**p-value**
Group			
Control	—	—	
Intervention	98	42, 153	<0.001
Time point			
baseline	—	—	
1 month	-8.0	-60, 44	0.8
3 months	-5.1	-59, 49	0.9
6 months	-7.9	-64, 48	0.8
1 year	-6.1	-59, 47	0.8
Age	-0.51	-2.3, 1.3	0.6
Sex			
Male	—	—	
Female	-9.7	-44, 24	0.6
Ejection Fraction (EF)	0.30	-1.6, 2.2	0.7
HbA1c	17	-7.3, 42	0.2
NYHA			
II	—	—	
III	8.3	-28, 45	0.6
IV	-1.3	-51, 48	>0.9

Effect	**Beta**	**95% CI[1]**	**p-value**
Alcoholic	-30	-130, 69	0.5
Obesity	23	-19, 65	0.3
Smoking	13	-24, 50	0.5
Hyperlipidemia	-30	-61, 1.9	0.065
Hypertension	-11	-50, 27	0.6
Arrythmias	-10	-41, 21	0.5
Valvular disease	-14	-64, 37	0.6
Coronary artery	11	-26, 49	0.6
Group * Time point			
Intervention * 1 month	-57	-133, 20	0.15
Intervention * 3 months	-58	-136, 20	0.15
Intervention * 6 months	-88	-168, -8.4	0.030
Intervention * 1 year	-89	-167, -11	0.026

[1] CI = Confidence Interval

9.8 The Perceived Social Support

The Greek version of the MSPSS measures the perceived social support in the dimensions of family/significant others and friends. Graph in Figure 7 shows the average scores across time, for the perceived social support (MSPSS) dimensions. At baseline, no difference was found between the IG and the CG (Table 56). The IG had higher perceived social support compared to the CG (p<0.001) at all dimensions at first month, three months, six months and in one year after the intervention (Tables 57,58,59,60 respectively). The multilevel model for the effect of the intervention on perceived social support showed a statistically significant effect of the intervention at all the time points after the intervention (p <= 0.003), in the overall perceived social support (Table 61). In the dimension of family/significant others Linear Mixed Model results showed a statistically significant effect of the intervention at all the time points after the intervention (p <= 0.007) (Table 62). In the dimension of friends, Linear Mixed Model results showed a statistically significant effect of the intervention at the 1st month (p = 0.009), 6 months (p < 0.001) and a year (p = 0.001) (Table 63).

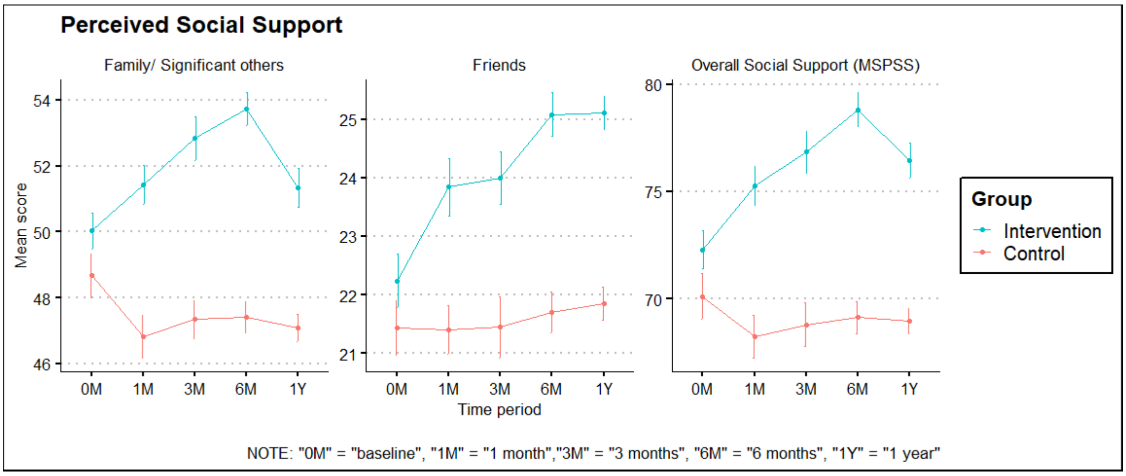

Figure 7: Perceived Social Support

Note: HIGHER scores indicate Higher perceived Sosial Support.

Table 56: Perceived Social Support at baseline

Dimension	**Overall**, N = 121[1]	**Control**, N = 65[1]	**Intervention**, N = 56[1]	**p-value**[2]
Family/ Significant others	49.3 (4.8)	48.7 (5.4)	50.0 (4.0)	0.12
Friends	21.8 (3.6)	21.4 (3.7)	22.2 (3.4)	0.2
Overall Social Support (MSPSS)	71.1 (7.8)	70.1 (8.6)	72.3 (6.5)	0.12

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 57: Perceived Social Support at 1 month

Dimension	**Overall**, N = 120[1]	**Control**, N = 64[1]	**Intervention**, N = 56[1]	**p-value**[2]
Family/ Significant others	48.8 (5.1)	46.8 (5.0)	51.4 (4.0)	<0.001
Friends	22.4 (3.4)	21.4 (3.2)	23.8 (3.2)	<0.001
Overall Social Support (MSPSS)	71.2 (7.9)	68.2 (7.7)	75.3 (6.1)	<0.001

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 58: Perceived Social Support at 3 months

Dimension	**Overall**, N = 113[1]	**Control**, N = 61[1]	**Intervention**, N = 52[1]	**p-value**[2]
Family/ Significant others	49.7 (5.1)	47.3 (4.2)	52.8 (4.3)	<0.001
Friends	22.6 (3.8)	21.4 (4.0)	24.0 (2.9)	<0.001
Overall Social Support (MSPSS)	72.3 (8.2)	68.8 (7.7)	76.8 (6.4)	<0.001

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 59: Perceived Social Support at 6 months

Dimension	**Overall**, N = 107[1]	**Control**, N = 58[1]	**Intervention**, N = 49[1]	**p-value**[2]
Family/ Significant others	50.3 (4.7)	47.4 (3.6)	53.7 (3.4)	<0.001
Friends	23.3 (3.1)	21.7 (2.7)	25.1 (2.6)	<0.001
Overall Social Support (MSPSS)	73.6 (7.4)	69.1 (5.7)	78.8 (5.5)	<0.001

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 60: Perceived Social Support at 1 year

Dimension	**Overall**, N = 100[1]	**Control**, N = 55[1]	**Intervention**, N = 45[1]	**p-value**[2]
Family/ Significant others	49.0 (4.1)	47.1 (3.1)	51.3 (4.0)	<0.001
Friends	23.3 (2.6)	21.9 (2.1)	25.1 (1.9)	<0.001
Overall Social Support (MSPSS)	72.3 (6.2)	68.9 (4.4)	76.4 (5.6)	<0.001

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 61: Linear Mixed Model Effect (LMME) for the effect of the Intervention on the overall Perceived Social Support (MSPSS)

Effect	**Beta**	**95% CI[1]**	**p-value**
Group			
Control	—	—	
Intervention	2.1	-0.53, 4.6	0.12
Time point			
baseline	—	—	
1 month	-2.6	-4.6, -0.48	0.016
3 months	-1.1	-3.2, 1.1	0.3
6 months	-1.3	-3.5, 0.95	0.3
1 year	-1.2	-3.3, 0.84	0.2
Age	-0.04	-0.15, 0.06	0.4
Sex			
Male	—	—	
Female	-1.2	-3.2, 0.84	0.2
Ejection fraction (EF)	0.06	-0.05, 0.17	0.3
HbA1c	-0.72	-2.1, 0.65	0.3
NYHA			
II	—	—	
III	0.51	-1.7, 2.7	0.6
IV	-0.98	-3.9, 1.9	0.5

Effect	**Beta**	**95% CI[1]**	**p-value**
Alcoholic	2.5	-3.5, 8.5	0.4
Obesity	1.3	-1.2, 3.7	0.3
Smoking	-1.9	-4.1, 0.33	0.095
Hyperlipidemia	0.17	-1.7, 2.0	0.9
Hypertension	-1.0	-3.3, 1.3	0.4
Arrythmias	-0.42	-2.3, 1.4	0.7
Valvular disease	0.30	-2.6, 3.2	0.8
Coronary artery	-2.4	-4.6, -0.14	0.038
Group * Time point			
Intervention * 1 month	6.0	2.8, 9.2	<0.001
Intervention * 3 months	4.9	1.7, 8.2	0.003
Intervention * 6 months	7.5	4.3, 11	<0.001
Intervention * 1 year	5.2	2.0, 8.3	0.001

[1] CI = Confidence Interval

Table 62: Linear Mixed Model Effect (LMME) for the effect of the Intervention on the Family/ Significant others (MSPSS)

Effect	**Beta**	**95% CI**[1]	**p-value**
Group			
Control	—	—	
Intervention	1.3	-0.29, 3.0	0.11
Time point			
baseline	—	—	
1 month	-2.3	-3.6, -0.93	<0.001
3 months	-1.1	-2.5, 0.26	0.11
6 months	-1.3	-2.7, 0.17	0.084
1 year	-1.5	-2.8, -0.17	0.028
Age	-0.02	-0.08, 0.05	0.6
Sex			
Male	—	—	
Female	-0.82	-2.0, 0.41	0.2
Ejection Fraction (EF)	0.03	-0.04, 0.10	0.4
HbA1c	-0.28	-1.1, 0.57	0.5
NYHA			
II	—	—	
III	0.72	-0.60, 2.0	0.3
IV	-0.30	-2.1, 1.5	0.7

Effect	**Beta**	**95% CI[1]**	**p-value**
Alcoholic	0.27	-3.4, 3.9	0.9
Obesity	0.83	-0.65, 2.3	0.3
Smoking	-1.1	-2.4, 0.22	0.10
Hyperlipidemia	-0.14	-1.3, 1.0	0.8
Hypertension	-0.34	-1.7, 1.1	0.6
Arrythmias	0.03	-1.1, 1.2	>0.9
Valvular disease	-0.01	-1.8, 1.8	>0.9
Coronary artery	-1.7	-3.1, -0.39	0.012
Group * Time point			
Intervention * 1 month	4.1	2.0, 6.1	<0.001
Intervention * 3 months	3.8	1.7, 5.9	<0.001
Intervention * 6 months	4.9	2.8, 6.9	<0.001
Intervention * 1 year	2.8	0.77, 4.8	0.007

[1] CI = Confidence Interval

Table 63: Linear Mixed Model Effect (LMME) for the effect of the intervention on the friends (MSPSS)

Effect	Beta	95% CI[1]	p-value
Group			
Control	—	—	
Intervention	0.72	-0.50, 1.9	0.2
Time point			
baseline	—	—	
1 month	-0.29	-1.2, 0.67	0.6
3 months	0.06	-0.94, 1.1	>0.9
6 months	-0.02	-1.0, 1.0	>0.9
1 year	0.27	-0.69, 1.2	0.6
Age	-0.02	-0.07, 0.03	0.4
Sex			
Male	—	—	
Female	-0.37	-1.4, 0.61	0.5
Ejection Fraction (EF)	0.03	-0.02, 0.09	0.2
HbA1c	-0.44	-1.1, 0.22	0.2
NYHA			
II	—	—	
III	-0.23	-1.3, 0.83	0.7
IV	-0.69	-2.1, 0.71	0.3

Effect	**Beta**	**95% CI[1]**	**p-value**
Alcoholic	2.2	-0.69, 5.2	0.13
Obesity	0.42	-0.78, 1.6	0.5
Smoking	-0.74	-1.8, 0.33	0.2
Hyperlipidemia	0.33	-0.58, 1.2	0.5
Hypertension	-0.70	-1.8, 0.42	0.2
Arrythmias	-0.45	-1.4, 0.45	0.3
Valvular disease	0.32	-1.1, 1.7	0.7
Coronary artery	-0.60	-1.7, 0.47	0.3
Group * Time point			
Intervention * 1 month	2.0	0.49, 3.4	0.009
Intervention * 3 months	1.1	-0.42, 2.6	0.2
Intervention * 6 months	2.6	1.2, 4.1	<0.001
Intervention * 1 year	2.4	0.95, 3.8	0.001

[1] CI = Confidence Interval

9.9 Diabetes related quality of life

The ADDQoL tool mesures the following diabetes related QoL dimensions: leisure activities, working life, journeys, holidays, physical health, family life, friendship and social life, rersonal relationship, sex life, physical appearance, self-confidence, motivation, people's reaction, feelings about future, financial situation, living conditions, dependence on others, freedom to eat and freedom to drink. Graph in Figure 8 shows the average scores across time, for the Diabetes related QoL dimensions.

At baseline, a difference was found between the CG and the IG with respect to leisure activities ($p = 0.034$), journeys ($p = 0.004$), people's reaction ($p = 0.015$), and dependence on others ($p < 0.001$), where the intervention had higher score. No other differences found between the two groups ($p > 0.05$) (Table 64). A difference was found between CG and I G with respect to: people's reaction ($p = 0.002$) and financial situation ($p=0.011$), with the IG having higher mean scores at the 1st month (Table 65). At three months, the IG had higher mean scores compared to the CG in almost all the dimensions ($p < 0.05$), with the exception of working life ($p = 0.4$), holidays ($p =0.7$), family life ($p=0.15$) and sex life ($p = 0.8$) (Table 66). At six months, the IG had higher mean scores compared to CG in almost all the dimensions ($p < 0.05$), with the exception of working life ($p = 0.2$), holidays ($p =0.074$), family life ($p=0.3$), rersonal relationship ($p = 0.081$), sex life ($p = 0.3$), and physical appearance ($p =0.3$) (Table 67). At one year, the IG had higher mean scores compared to CG, in almost all the dimensions ($p < 0.05$), with the exception of holidays ($p =0.6$), friendship and social life ($p=0.083$), family life ($p=0.6$), personal relationship ($p = 0.6$) and physical appearance ($p =0.3$) (Table 68).The multilevel model for the effect of the intervention on the diabetes dependent QoL showed a statistically significant effect of the intervention at three months ($p = 0.012$) and six months ($p < 0.001$) in the overall diabetes dependent QoL (Table 69).

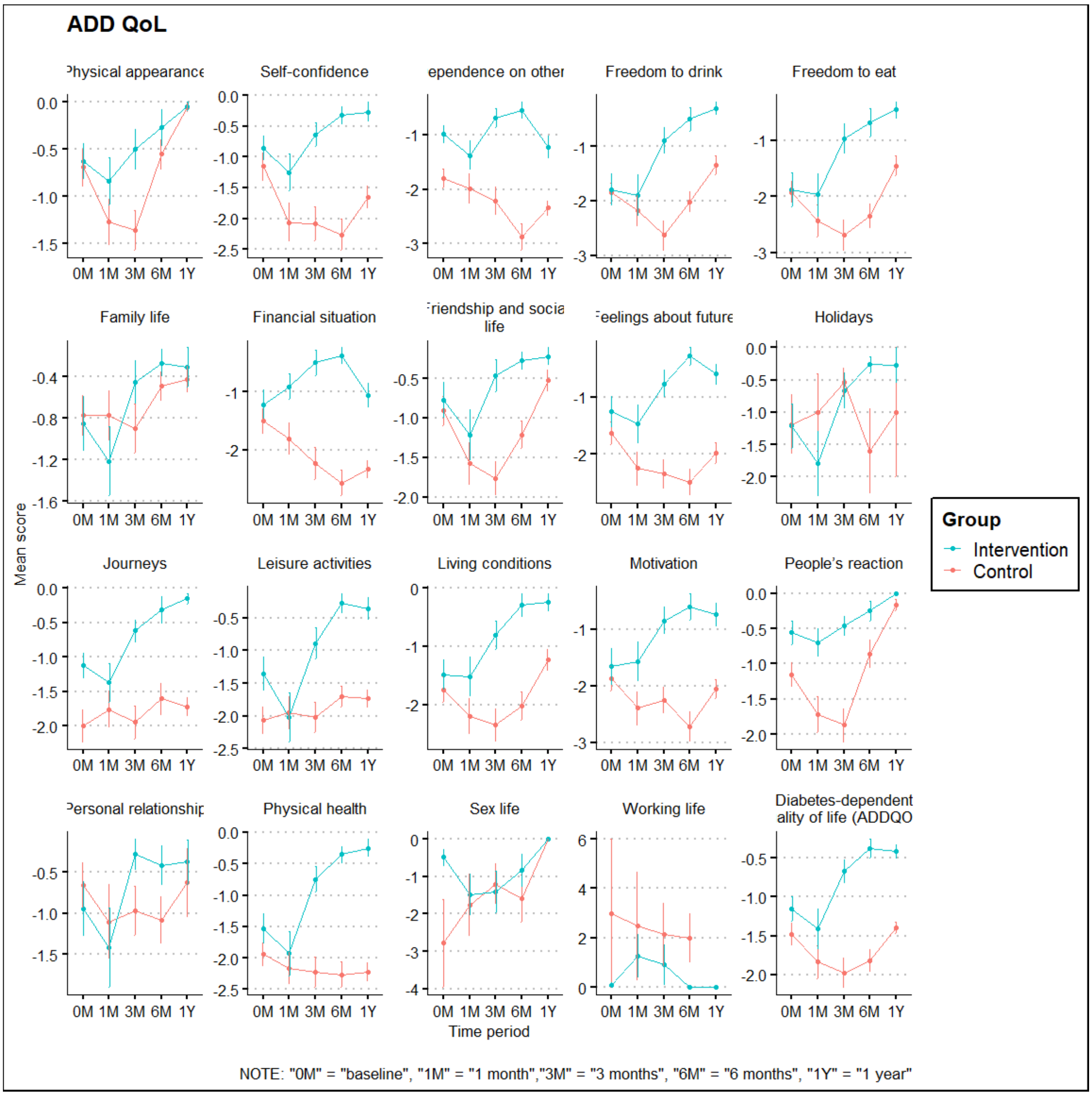

Figure 8: Diabetes related QoL (ADDQoL)

Note: Higher scores indicate better quality of life. [e.g. -2 is higher than -1]

Table 64: Diabetes related QoL (ADDQoL) at baseline

Dimension	**Overall**, N = 121[1]	**Control**, N = 65[1]	**Intervention**, N = 56[1]	**p-value**[2]
Leisure activities	-1.7 (1.8)	-2.1 (1.6)	-1.4 (1.9)	0.034
Working life	0.7 (2.4)	3.0 (5.2)	0.1 (0.3)	0.4
Journeys	-1.6 (1.7)	-2.0 (1.8)	-1.1 (1.4)	0.004
Holidays	-1.2 (2.0)	-1.2 (2.1)	-1.2 (2.0)	>0.9
Physical health	-1.8 (1.6)	-1.9 (1.5)	-1.5 (1.8)	0.2
Family life	-0.8 (1.7)	-0.8 (1.5)	-0.9 (2.0)	0.8
Friendship and social life	-0.8 (1.6)	-0.9 (1.5)	-0.8 (1.7)	0.6
Personal relationship	-0.8 (1.8)	-0.7 (1.5)	-0.9 (2.1)	0.5
Sex life	-1.1 (2.2)	-2.8 (3.5)	-0.5 (1.1)	0.089
Physical appearance	-0.7 (1.5)	-0.7 (1.6)	-0.6 (1.4)	0.8
Self-confidence	-1.0 (1.7)	-1.2 (1.8)	-0.9 (1.5)	0.3
Motivation	-1.8 (2.0)	-1.9 (1.7)	-1.7 (2.3)	0.6
People’s reaction	-0.9 (1.4)	-1.2 (1.4)	-0.6 (1.2)	0.015
Feelings about future	-1.5 (1.8)	-1.6 (1.6)	-1.3 (1.9)	0.3
Financial situation	-1.4 (1.8)	-1.5 (1.7)	-1.2 (1.8)	0.4
Living conditions	-1.6 (1.8)	-1.7 (1.8)	-1.5 (1.9)	0.4
Dependence on others	-1.4 (1.4)	-1.8 (1.4)	-1.0 (1.2)	<0.001
Freedom to eat	-1.9 (1.9)	-1.9 (1.6)	-1.9 (2.2)	0.9
Freedom to drink	-1.8 (1.8)	-1.8 (1.5)	-1.8 (2.1)	0.9
Diabetes-dependent quality of life (ADDQOL)	-1.3 (1.2)	-1.5 (1.2)	-1.2 (1.2)	0.13

Dimension	**Overall**, N = 121[1]	**Control**, N = 65[1]	**Intervention**, N = 56[1]	**p-value**[2]

[1]Mean (SD)

[2]Welch Two Sample t-test

Table 65: Diabetes related QoL (ADDQoL) at 1 month

Dimension	**Overall**, N = 120[1]	**Control**, N = 64[1]	**Intervention**, N = 56[1]	**p-value**[2]
Leisure activities	-2.0 (2.4)	-2.0 (2.0)	-2.0 (2.8)	0.9
Working life	1.6 (3.2)	2.5 (4.4)	1.3 (2.8)	0.6
Journeys	-1.6 (2.1)	-1.8 (2.1)	-1.4 (2.1)	0.3
Holidays	-1.6 (2.8)	-1.0 (2.3)	-1.8 (2.9)	0.3
Physical health	-2.1 (2.3)	-2.2 (2.0)	-1.9 (2.7)	0.6
Family life	-1.0 (2.2)	-0.8 (1.9)	-1.2 (2.5)	0.3
Friendship and social life	-1.4 (2.2)	-1.6 (2.1)	-1.2 (2.4)	0.4
Personal relationship	-1.3 (2.7)	-1.1 (2.4)	-1.4 (2.9)	0.6
Sex life	-1.6 (3.0)	-1.8 (3.2)	-1.5 (2.8)	0.8
Physical appearance	-1.1 (1.9)	-1.3 (1.9)	-0.8 (1.9)	0.2
Self-confidence	-1.7 (2.4)	-2.1 (2.5)	-1.3 (2.2)	0.062
Motivation	-2.0 (2.4)	-2.4 (2.3)	-1.6 (2.6)	0.067
People’s reaction	-1.2 (1.8)	-1.7 (2.0)	-0.7 (1.5)	0.002
Feelings about future	-1.9 (2.4)	-2.2 (2.2)	-1.5 (2.5)	0.078
Financial situation	-1.4 (2.0)	-1.8 (2.2)	-0.9 (1.6)	0.011
Living conditions	-1.9 (2.5)	-2.2 (2.4)	-1.5 (2.5)	0.14

Dimension	**Overall**, N = 120[1]	**Control**, N = 64[1]	**Intervention**, N = 56[1]	**p-value**[2]
Dependence on others	-1.7 (2.1)	-2.0 (2.2)	-1.4 (2.0)	0.12
Freedom to eat	-2.2 (2.6)	-2.4 (2.3)	-2.0 (2.8)	0.3
Freedom to drink	-2.0 (2.5)	-2.2 (2.2)	-1.9 (2.8)	0.5
Diabetes-dependent quality of life (ADDQOL)	-1.6 (1.8)	-1.8 (1.7)	-1.4 (1.9)	0.2

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 66: Diabetes related QoL (ADDQoL) at 3 months

Dimension	**Overall**, N = 113[1]	**Control**, N = 61[1]	**Intervention**, N = 52[1]	**p-value**[2]
Leisure activities	-1.5 (1.8)	-2.0 (1.8)	-0.9 (1.8)	<0.001
Working life	1.4 (2.9)	2.1 (3.3)	0.9 (2.7)	0.4
Journeys	-1.3 (1.7)	-2.0 (1.9)	-0.6 (1.1)	<0.001
Holidays	-0.6 (1.3)	-0.5 (0.8)	-0.7 (1.5)	0.7
Physical health	-1.5 (1.8)	-2.2 (1.9)	-0.8 (1.5)	<0.001
Family life	-0.7 (1.7)	-0.9 (1.8)	-0.5 (1.4)	0.15
Friendship and social life	-1.2 (1.7)	-1.8 (1.7)	-0.5 (1.5)	<0.001
Personal relationship	-0.6 (1.4)	-1.0 (1.7)	-0.3 (1.1)	0.056
Sex life	-1.3 (2.6)	-1.2 (2.1)	-1.4 (2.9)	0.8
Physical appearance	-1.0 (1.6)	-1.4 (1.6)	-0.5 (1.5)	0.005

Dimension	**Overall**, N = 113[1]	**Control**, N = 61[1]	**Intervention**, N = 52[1]	**p-value**[2]
Self-confidence	-1.4 (1.9)	-2.1 (2.1)	-0.6 (1.4)	<0.001
Motivation	-1.6 (1.9)	-2.2 (1.7)	-0.8 (1.8)	<0.001
People’s reaction	-1.2 (1.7)	-1.9 (1.8)	-0.5 (1.0)	<0.001
Feelings about future	-1.6 (1.9)	-2.3 (1.9)	-0.8 (1.7)	<0.001
Financial situation	-1.4 (2.1)	-2.2 (2.2)	-0.5 (1.5)	<0.001
Living conditions	-1.6 (2.1)	-2.4 (2.2)	-0.8 (1.8)	<0.001
Dependence on others	-1.5 (1.8)	-2.2 (2.0)	-0.7 (1.3)	<0.001
Freedom to eat	-1.9 (2.2)	-2.7 (2.1)	-1.0 (1.9)	<0.001
Freedom to drink	-1.8 (2.1)	-2.6 (2.1)	-0.9 (1.8)	<0.001
Diabetes-dependent quality of life (ADDQOL)	-1.4 (1.4)	-2.0 (1.4)	-0.7 (1.1)	<0.001

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 67: Diabetes related QoL (ADDQoL) at 6 months

Dimension	**Overall**, N = 107[1]	**Control**, N = 58[1]	**Intervention**, N = 49[1]	**p-value**[2]
Leisure activities	-1.0 (1.3)	-1.7 (1.2)	-0.3 (1.0)	<0.001
Working life	0.4 (1.1)	2.0 (1.7)	0.0 (0.0)	0.2
Journeys	-1.0 (1.7)	-1.6 (1.7)	-0.3 (1.4)	<0.001
Holidays	-0.6 (1.3)	-1.6 (2.1)	-0.3 (0.8)	0.074
Physical health	-1.4 (1.6)	-2.3 (1.5)	-0.4 (0.9)	<0.001

Dimension	**Overall**, N = 107[1]	**Control**, N = 58[1]	**Intervention**, N = 49[1]	**p-value**[2]
Family life	-0.4 (1.0)	-0.5 (1.0)	-0.3 (0.9)	0.3
Friendship and social life	-0.8 (1.2)	-1.2 (1.3)	-0.3 (0.7)	<0.001
Personal relationship	-0.7 (1.5)	-1.1 (1.4)	-0.4 (1.5)	0.081
Sex life	-1.1 (2.1)	-1.6 (2.2)	-0.8 (2.1)	0.3
Physical appearance	-0.4 (1.3)	-0.6 (1.2)	-0.3 (1.3)	0.3
Self-confidence	-1.4 (1.8)	-2.3 (1.9)	-0.3 (0.9)	<0.001
Motivation	-1.8 (2.1)	-2.7 (2.0)	-0.6 (1.7)	<0.001
People's reaction	-0.6 (1.4)	-0.9 (1.5)	-0.3 (1.0)	0.017
Feelings about future	-1.5 (1.8)	-2.5 (1.7)	-0.3 (1.0)	<0.001
Financial situation	-1.6 (1.8)	-2.6 (1.6)	-0.4 (0.9)	<0.001
Living conditions	-1.2 (1.8)	-2.0 (1.8)	-0.3 (1.4)	<0.001
Dependence on others	-1.8 (1.9)	-2.9 (1.8)	-0.5 (1.0)	<0.001
Freedom to eat	-1.6 (1.9)	-2.4 (1.6)	-0.7 (1.8)	<0.001
Freedom to drink	-1.3 (1.7)	-2.0 (1.5)	-0.5 (1.5)	<0.001
Diabetes-dependent quality of life (ADDQOL)	-1.2 (1.2)	-1.8 (1.1)	-0.4 (0.8)	<0.001

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 68: Diabetes related QoL (ADDQoL) at 1 year

Dimension	**Overall**, N = 100[1]	**Control**, N = 55[1]	**Intervention**, N = 45[1]	**p-value**[2]
Leisure activities	-1.1 (1.3)	-1.7 (1.0)	-0.4 (1.2)	<0.001
Working life	0.0 (0.0)	NA (NA)	0.0 (0.0)	
Journeys	-1.0 (1.1)	-1.7 (1.0)	-0.2 (0.5)	<0.001
Holidays	-0.4 (1.1)	-1.0 (1.4)	-0.3 (1.0)	0.6
Physical health	-1.3 (1.4)	-2.2 (1.0)	-0.3 (0.9)	<0.001
Family life	-0.4 (1.1)	-0.4 (0.9)	-0.3 (1.3)	0.6
Friendship and social life	-0.4 (0.9)	-0.5 (1.0)	-0.2 (0.8)	0.083
Personal relationship	-0.5 (1.1)	-0.6 (1.2)	-0.4 (1.1)	0.6
Sex life	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	
Physical appearance	-0.1 (0.4)	-0.1 (0.4)	0.0 (0.3)	0.9
Self-confidence	-1.0 (1.4)	-1.6 (1.3)	-0.3 (1.1)	<0.001
Motivation	-1.5 (1.4)	-2.1 (1.2)	-0.7 (1.3)	<0.001
People’s reaction	-0.1 (0.5)	-0.2 (0.6)	0.0 (0.0)	0.049
Feelings about future	-1.4 (1.4)	-2.0 (1.3)	-0.6 (1.2)	<0.001
Financial situation	-1.8 (1.4)	-2.3 (1.1)	-1.1 (1.4)	<0.001
Living conditions	-0.8 (1.3)	-1.2 (1.3)	-0.2 (1.0)	<0.001
Dependence on others	-1.8 (1.3)	-2.3 (1.0)	-1.2 (1.4)	<0.001
Freedom to eat	-1.0 (1.2)	-1.5 (1.3)	-0.5 (0.9)	<0.001
Freedom to drink	-0.9 (1.2)	-1.3 (1.3)	-0.3 (0.8)	<0.001
Diabetes-dependent quality of life (ADDQOL)	-1.0 (0.7)	-1.4 (0.5)	-0.4 (0.6)	<0.001

Dimension	**Overall**, N = 100[1]	**Control**, N = 55[1]	**Intervention**, N = 45[1]	**p-value**[2]

[1]Mean (SD)

[2]Welch Two Sample t-test

Table 69: Linear Mixed Model Effect (LMME) for the effect of the Intervention on the Overall Diabetes-dependent quality of life (ADDQOL)

Effect	**Beta**	**95% CI**[1]	**p-value**
Group			
Control	—	—	
Intervention	0.27	-0.19, 0.74	0.2
Time point			
baseline	—	—	
1 month	-0.27	-0.64, 0.11	0.2
3 months	-0.32	-0.71, 0.07	0.11
6 months	-0.34	-0.75, 0.07	0.11
1 year	0.12	-0.26, 0.50	0.5
Age	0.00	-0.02, 0.02	0.8
Sex			
Male	—	—	
Female	-0.12	-0.46, 0.23	0.5
Ejection Fraction (EF)	0.01	-0.01, 0.03	0.3
HbA1c	-0.35	-0.59, -0.12	0.003
NYHA			
II	—	—	
III	-0.16	-0.54, 0.21	0.4
IV	-0.28	-0.78, 0.22	0.3

Effect	**Beta**	**95% CI[1]**	**p-value**
Alcoholic	-0.23	-1.2, 0.78	0.7
Obesity	0.43	0.00, 0.86	0.050
Smoking	0.30	-0.08, 0.68	0.12
Hyperlipidemia	0.23	-0.09, 0.55	0.2
Hypertension	-0.25	-0.64, 0.15	0.2
Arrythmias	-0.03	-0.35, 0.29	0.9
Valvular disease	0.39	-0.12, 0.90	0.13
Coronary artery	-0.16	-0.54, 0.22	0.4
Group * Time point			
Intervention * 1 month	-0.03	-0.58, 0.52	>0.9
Intervention * 3 months	0.72	0.16, 1.3	0.012
Intervention * 6 months	1.0	0.44, 1.6	<0.001
Intervention * 1 year	0.53	-0.04, 1.1	0.067

[1] CI = Confidence Interval

9.10 Reliability of The Tools

Reliability of the tools was measured using the internal consistency index of Cronbach's alpha. Cronbach's alpha values was greater than (>) 0.70, which is considered satisfactory for all the tools with the exception of the IPAQ questionaire that showed ‹0.70 (0.58 for the dimension of walking, 0.25 for the dimension of moderate exercise and 0.20 for the vigorous exercise). One possible explanation may be the fact that the IPAQ is a self-reported physical activity questionaire, not based on a likert scale but had broad questions that respondents may found too hard to think about. In the IPAQ the subjects are asked to answer in order to record the number of days (frequency) and the number of minutes per day (duration) of their participation in all kinds of vigorous, moderate and walking physical activity during the last seven days. The reliability index for the tools' dimensions is shown in Table 70.

Table 70: Tools' internal consistency index (baseline measurements) Gr9EHFScBS reliability

Scale	Cronbach's a
Adhering to Recommendations	0.66
Fluid and sodium Management	0.84
Physical activity and recognition of deteriorating symptoms	0.77

HADS reliability

Scale	Cronbach's a
Anxiety	0.88
Depression	0.81

IPAQ reliability

Scale	Cronbach's a
Walking	0.58
Moderate exercise	0.25
Vigorous exercise	0.20

MLHFQ reliability

Scale	Cronbach's a
Physical	0.97
Emotional	0.89
Social	0.83

SCHFI reliability

Scale	Cronbach's a
Maintenance	0.81
Management	0.80
Self-confidence	0.94

MSPSS reliability

Scale	Cronbach's a
Family/ Significant others	0.93
Friends	0.95

ADDQoL reliability

Scale	Cronbach's a
Diabetes-dependent quality of life (ADDQOL)	0.92

9.11 Level of Glycosylated Haemoglobin

Graph in Figure 9 shows the average HbA1c levels across time. The IG has significantly lower HbA1c values on average, compared to the CG (Table 71). The multilevel model for the effect of the intervention on the HbA1c showed a statistically significant effect of the intervention at all time points (1M: $p = 0.012$, 3M: $p < 0.001$, 6M: $p < 0.001$, 1Y: $p < 0.001$) (Table 72).

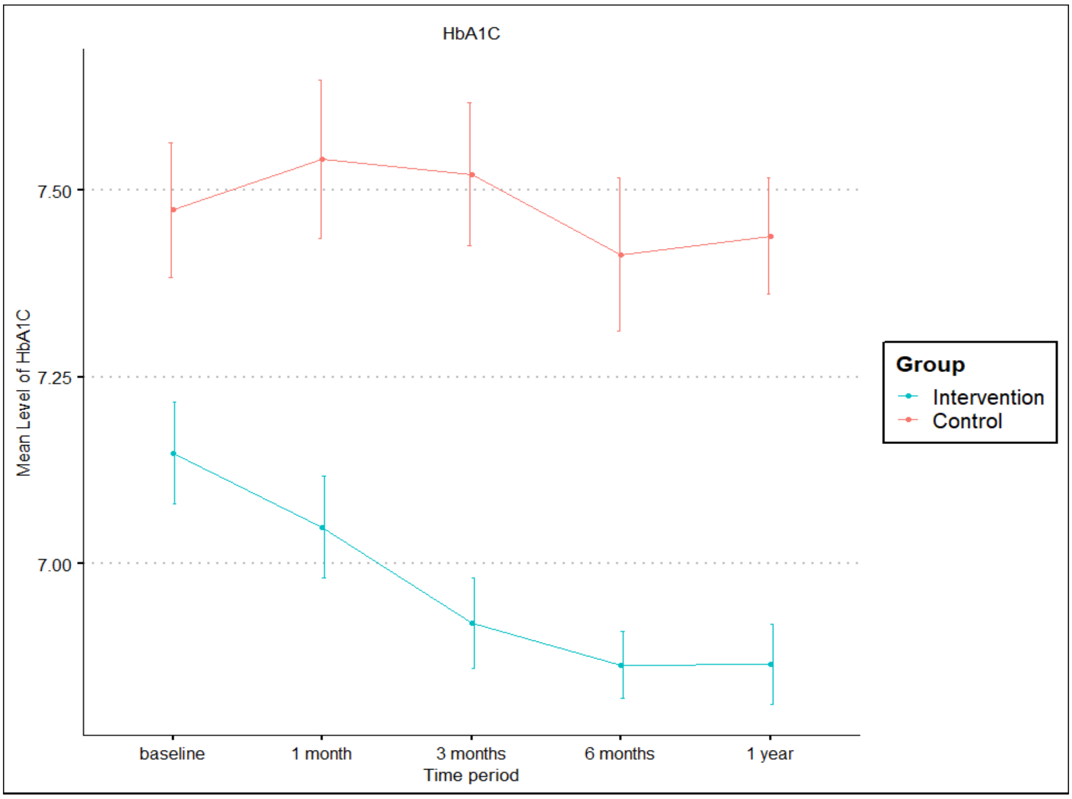

Figure 9: HbA1c levels across time and groups

Table 71: Mean Level of HbA1c across time and groups

Time-point	**Control**, N = 65[1]	**Intervention**, N = 56[1]	**p-value**[2]
baseline	7.5 (0.7)	7.1 (0.5)	0.005
3 months	7.5 (0.7)	6.9 (0.4)	<0.001
6 months	7.4 (0.7)	6.9 (0.3)	<0.001
1 year	7.4 (0.6)	6.9 (0.4)	<0.001

[1] Mean (SD)

[2] Welch Two Sample t-test

Table 72: Linear Mixed Model Effect (LMME) for the effect of the intervention on the HbA1c

Effect	**Beta**	**95% CI**[1]	**p-value**
Group			
Control	—	—	
Intervention	-0.36	-0.60, -0.12	0.003
Time point			
baseline	—	—	
1 month	0.05	-0.03, 0.13	0.2
3 months	0.04	-0.04, 0.13	0.3
6 months	0.02	-0.07, 0.11	0.7
1 year	0.03	-0.05, 0.12	0.4
Age	0.01	-0.01, 0.02	0.3
Sex			
Male	—	—	
Female	-0.01	-0.26, 0.23	>0.9
Ejection Fraction (EF)	-0.01	-0.02, 0.00	0.15
NYHA			
II	—	—	
III	0.14	-0.13, 0.40	0.3
IV	0.12	-0.22, 0.47	0.5
Alcoholic	0.09	-0.61, 0.79	0.8
Obesity	0.06	-0.24, 0.36	0.7

Effect	**Beta**	**95% CI[1]**	**p-value**
Smoking	-0.05	-0.31, 0.21	0.7
Hyperlipidemia	0.14	-0.09, 0.36	0.2
Hypertension	0.05	-0.23, 0.33	0.7
Arrythmias	0.02	-0.20, 0.24	0.9
Valvular disease	0.07	-0.28, 0.42	0.7
Coronary artery	0.00	-0.26, 0.26	>0.9
Group * Time point			
Intervention * 1 month	-0.15	-0.27, -0.03	0.012
Intervention * 3 months	-0.27	-0.40, -0.15	<0.001
Intervention * 6 months	-0.28	-0.41, -0.16	<0.001
Intervention * 1 year	-0.30	-0.43, -0.18	<0.001
[1]CI = Confidence Interval			

9.12 Survival Analysis

Survival analysis was studied categorizing it, into two separate events; a) *acute events* and b) *death events due to heart failure*.

9.12.1 Acute Events

Acute events were either readmissions in the hospital or Emergency Room (ER) visits. At the period from recruitment to 1 month, there were 3/65 (4.6 %) acute events for the CG and 2/56 (3.6%) acute events for the IG. No difference in the prevalence of events between the two groups (p >0.9)) was found. After 1 month and until 3 months time point after the intervention, the CG (7/64 (10.9%) had more acute events compared to the IG (3/56 (5.4%)) (p=0.51). After 3 months and until the 6-month time point after the intervention, the CG (12/61 (19.7%)) had more acute events compared to the IG ((6/52 (11.5%)) (p=0.3). Between 6 months and until 1 year time point after the intervention, the IG (0/49 (0.0%)) hadn't any acute event compared to the CG that had 8/58 (13.8%) (p= 0.007) acute events (Table 73).

Table 73: Acute events

period	Control	Intervention	p
<1M	3 (4.6%)	2 (3.6%)	>0.9
1M ~ <3M	7 (10.9%)	3 (5.4%)	0.51
3M ~ <6M	12 (19.7%)	6 (11.5%)	0.3
6m ~ < 1Y	8 (13.8%)	0 (0.0%)	0.007

Note: Proportion at each time-point according to the patients in the study after the drop outs
Control: 65, 64, 61, 58 at <M, 1M~3M, 3M~6M, and 6M~1Y respectively,
Intervention: 56, 56, 52, 49 at <M, 1M~3M, 3M~6M, and 6M~1Y respectively

9.12.2 Death Events

There were no significant differences in the mortality across the two groups. This was observed in all time points (Table 74).

Table74: Death events

period	Control	Intervention	p
<1M	1 (1.5%)	0 (0.0%)	>0.9
1M ~ <3M	2 (3.1%)	3 (5.4%)	0.66
3M ~ <6M	3 (4.9%)	1 (1.9%)	0.62
6m ~ < 1Y	1 (1.7%)	1 (2.0%)	>0.9

Note: Proportion at each time-point according to the patients in the study after the drop outs
Control: 65, 64, 61, 58 at <M, 1M~3M, 3M~6M, and 6M~1Y respectively,
Intervention: 56, 56, 52, 49 at <M, 1M~3M, 3M~6M, and 6M~1Y respectively

9.12.3 All Events (acute events and death events)

When considering both; acute and death events after 6 months and until 1 year time point, the CG [9/58 (15.5%)] showed more acute events compared to the IG [1/49 (2%)] (p = 0.02) (Table 75).

Table 75: All events (acute events and death events)

period	Control	Intervention	p
<1M	4 (6.2%)	2 (3.6%)	0.69
1M ~ <3M	9 (14.1%)	6 (10.7%)	0.59
3M ~ <6M	15 (24.6%)	7 (13.5%)	0.16
6m ~ < 1Y	9 (15.5%)	1 (2.0%)	0.02

Note: Proportion at each time-point according to the patients in the study after the drop outs
Control: 65, 64, 61, 58 at <M, 1M~3M, 3M~6M, and 6M~1Y respectively,
Intervention: 56, 56, 52, 49 at <M, 1M~3M, 3M~6M, and 6M~1Y respectively

10. DISCUSSION

The current supportive care management program was based in a pragmatic methodology approach that was not used in previous RCTs like the MEETinCY in which a standardrised approach has been used. The pragmatic methodology that used in the 'SupportHeart' reseach study has an intensive intervention, which started rapidly and in early stages based on a patient – centred directed quidelines, and was rapidly accepted by the patients in the IG because it improved their HR-QoL symptoms and acute events. The pragmatic methodology investigates reality and different ways and approaches to investigate a research problem; so it could be better understood and managed. It enables researchers to conduct research in an innovative and dynamic way to find solutions to a research problem. A pragmatic study is based on an individual decision maker in a real-world situation lke those that patients with HF-DM experienced (Giuseppe et al., 2023). During the meetings in the current study, a patient was diagnosed with DM and amyloidosis (Philippou et al., 2023).The clinical case of the above patient was published and is presented in Appendix XXIII. In the intervention of the 'SupportHeart' program, supportive care offered according to patients' needs following the illness trajectory (Goodlin et al. 2004, Buck & Zambroski 2012).

10.1 Risk factors associated with the development of heart failure in diabetic patients

The mean age of the participants in the current, study was 73.9 years old and the literature also refered that older age in DM is an important risk factor for the incident of HF (Park 2021). Most of the participants were males (66%) and the literature referred that there is greater incidence of HF in men (Roger et al. 2013, Mozaffarian et al. 2016). While women have a lower incidence rate to develop HF compared to men, approximately half of the prevalent cases in HFpEF, is more common in women (Christ et al. 2016, Christiansen et al. 2017). The reasons for this data between the sexes are not clear, but perhaps this is because severe HF symptoms are presented later and women have a higher life expectancy compared to men (Dunlay et al., 2017). Another reason perhaps is the lack of therapeutic options in HFpEF (Lawson et al., 2019). Approximately in diabetic patients ≥ 65 years old, 74.3% had hypertension (Korean

Diabetes Association 2020, Park 2021). DM and hypertension are refered as independent risk factors for HF and their concurrence predispose to the development of HF (Park 2021). In this study the most frequent risk factor from the clinical characteristics of the participants was hypertension (78%) (p= 0.016). Similarly, Peres et al (2019) supports that the risk factors for the development of CVD in DM2 patients except of hypertension is hyperlipidemia and obesity, factors that was found as risk factors in the current study with the frequency of hyperlipidemia present in 61% of the patients and obesity in 16%.

However, the fact that this study is a secondary analysis of the ‘SupportHeart’ RCT, the randomization could not be achieved for the particular population (HF patients with DM) so some differences that exist between the IG and the CG are justified. Therefore, it is very important to conduct RCTs exclusively in this group of patients with HF and the comorbidity of DM. There were no patients at NYHA stage I in the current study but most of them were classified at NYHA stage III 69 (57%)], CG 35 (54%) and IG 34 (61%)] (p= 0.2). This could be explained by the fact that patients with HFpEF are mostly misdiagnosed since patients aτ NYHA stage I are asymptomatic with no any physical limitation and with LVEF is ≥ 50%. Patients with HFpEF are older, most of them women, obese, and more commonly have a history of hypertension and atrial fibrillation and a history of myocardial infarction is less common (Kapoor et al., 2016).

10.2 Health Related Quality of Life in patients with Heart Failure and Diabetes Mellitus

Patients with DM and HF have worse HR-QoL than patients with HF alone (Fotos et al., 2013). HR-QoL depends on several physical, emotional, and social factors and perceived individually by each patient (Gallangher et al., 2019). In the current study at the 1 year, HF-DM patients in the IG had better HR-QoL compared to the CG in all dimensions of the MLHFQ tool; the physical dimension (p = 0.015), the emotional dimension (p = 0.023), the social dimension (p = 0.4), and the overal HR- QoL (p = 0.024). It is very crucial to find ways to improve HR-QoL in HF patients with DM since a low health status lead to poor prognosis for these chronic dideases (McMurray et al., 2012). HF in diabetic patients is an important health problem and vice versa and these two conditions leads to poor HR-QoL and to severe complications that are associated with the two diseases (Einarson et al. 2018, Gulsin et al. 2019).

According to the cut-off point in the MLHFQ tool, a lower score indicates better HR-QoL. Scores less than 24, from 24 to 45, and above 45 indicates a good, moderate, and poor HR-QoL, respectively (Garin et al. 2013). In the current study at baseline the IG [21.6 (19.2)] had good HR-QoL and the CG [28.7 (24.1)] had moderate HR-QoL but no difference at 1 month and 3 months was observed betweeen the two groups. Both groups had good HR-QoL; at 1 month CG 11.8 (15.9) IG 13.9 (19.6) and at 3 months CG 8.6 (13.0) and IG 5.6 (11.2). At 6 months and one year after the intervention, the IG had beter HR-QoL compared to the CG for all the dimensions and for the overall HR-QoL of the MLHFQ except for the social dimension in 6 months, which was the same for the two groups. In a year after the intervention, the social dimension showed better HR-QoL for the patients in the IG compared with the CG. Fitzsimons and Strachan (2012) support that physical and emotional health are the most challenging care needs of patients with HF and in the IG was found to be gradually improved 6 months after the intervention started. Patients in the IG needed more time to improve the social dimension of the HR-QoL, since they may experience limitations in their daily lives due to the nature of the commorbidities of HF and DM. Aso the improvement in the different dimensions and aspects of the HR-QoL may not come at the same time (Heo et al. 2009, Garin et al. 2013). Patients with HF-DM give priority first to improve their life-threatening conditions such as dyspnea and shortness of breath, and not to manage their hyperglycaemia or their social needs (Kerr et al 2007).

10.3 Perceived Social Support

The results in all dimensions of the MSPSS, showed higher perceived social support in HF-DM patients in the IG compared with the CG.; perceived social support from family/sifnificant others and from friends. Perceived social support is the expectation that patients have from the society and no from the HPs, including family members and friends, when they need help during a disease (Graven et al., 2014). Patients who have sufficient perceived social support feel confident in dealing with the complex factors related to their disease (Sorensen et al., 2009). Social support improves the ability of patients to adhere to a healthy lifestyle, making individuals more adaptable with the various aspects of chronic diseases such as HF and DM (Koetsenruijter et al., 2015). Social support, as a psychological factor, promotes healthy behaviors in chronic conditions (Morishita et al., 2017). Koetsenruijter et al. (2015) also supports that despite the fact that self-care is an individual factor; it is under the infuence of social support and is significantly associated with diabetic self-care behaviors. Social support can act, as a buffer to daily aggravating situations arising from HF -DM and is very important for patients to handle and cope with HF and DM related stressors (D'Zurilla et al., 2002). In the current study patients in the IG received higher perceived social support in compared with the CG since they were motivated and supported throuh empowerment during the program through monthly meetings via conversations, educational sessions, companionship, practical issues as well as personal issues like psychological support in cases that a spouse passed away. In addition, the research team got in touch with the patients by telephone once a month and patients could call a member from the research team for information or seek for help whenever they needed. Caregivers were also invited in the meetings and got support and could be involved in the program. Social support was quided by nurses through supportive care, which may lead in improvement of self-care management and adopting healthy behaviour, through the involvement of both; the patients and their family/caregivers (Sayers et al., 2008). In the current study there were lots of missing values in the MSPSS and this was because the tool was not used in the pilot study of the 'SupportHeart' from the baseline, in first month and in three months. Then it was considered important to be used in 'SupportHeart' RCT, since patients with enough perceived social support, feel confident in dealing with the complex factors related to chronic diseases (Sorensen et al,. 2009).

10.4 Anxiety and depression

In the current study at three months after the intervention, six months, and in one year the IG had lower emotional distress compared to the CG. At one year after the intervention p‹0.001 in all the dimensions of the tool. The multilevel model for the effect of the intervention on the HADS in the overall emotional distress and the Linear Mixed Model results, did not show any statistically significant effect of the intervention, at any of the time points after the intervention ($p > 0.05$) at the dimension of anxiety and at the dimension of depression ($p= 0.004$) perhaps due to the confound factors but clinically a declining trend was observed three months after the intervention. Previous studies had shown that exercise and cognitive behavioural therapy might improve symptoms of anxiety and depression as well as the HR-QoL in patients with HF (Gary et al. 2010, Pan et al. 2013, Tully et al. 2015). In the current study perhaps for the reduction of psychological stress mempers of the research team could use some problem-based coping strategies and be ensuring that patients will report any symptoms and provide the necessary medical information to fix any issue. In the research team, none of the researchers was sepecialist in psychology or mental issues and in pragmatic studies, the intervention is better to be delivered from specialists in order to be abe to find solutions to a problem based on terms that are applicable to peoples' experiences and are unique for each individual. More involvement also of the family and caregivers in the program could helped more to the reduction of anxiety, depression and emotional distress of the patients because a friendly and supportive environment created between patients, family/ caregivers, and the members in the research team could reduced any distress.

10.5 Self-care management of Patients with Heart Failure and Diabetes Mellitus

Self-care has a leading role for the management of chronic diseases like HF and DM based on patients' knowledge, background, capability and concerns (Ekman et al 2011, McMurray et al 2012). Demands of self-care are extremely increased when patients have HF and DM, simultaneously (Ha et al., 2016). Comorbidities like DM makes HF self-care more complicated. Patients must have the apropriate knowlege to be able to manage the two conditions with anything is related to either HF or DM or both (Graven & Grant., 2011). A self –care is "the ability of individuals, families and communities to promote health, prevent disease, maintain health, and to cope with illness and disability with or without the support of a health-care provider" (W.H.O, 2013).

It is a decision-making process, which involves the choice of behaviors that maintain physiologic stability (maintenance) and the response to symptoms when they occur (management) (Riegel & Dickson, 2008). The self-care maintenance refers to a healthy lifestyle, adhere to the pharmacotherapy and monitor symptoms. Symptom monitoring is a crucial component into self-care management and it considers decision-making in response to symptoms. Self-care management is an active process that begins with recognizing a change in health, like a shortness of breath or edema, evaluating the change, deciding to take action, implementing an action like take an extra diuretic dose and evaluating the treatment implemented (Riegel & Dickson, 2008). Self-care involves patients be able to adopt strategies to face a symptom and be able to evaluate if an action helped a specific condition (Jessup et al. 2003, Ha et al. 2016). In the current study patients from the IG had higher self care attitudes in all SCHFI dimensions including self-confidence, maintenance and management and the mean dimensions score ($\bar{x}$ = 63.8 (SD = 7.0) at 1 month were increased compared to baseline in the overall self-care management. At 3 months the mean ($\bar{x}$ = 68.9 (SD = 5.3) dimension scores of the IG were increased compared to 1 month and at 6 months the mean ($\bar{x}$ = 73.4 (SD = 5.1) dimension scores of the IG were increased compared to the 3 months.

Patients in the IG had higher self-care attitudes in all self –care behaviour scales in all dimensions of the EHFScBS questionaire compared with the CG. The dimensions included: adherering to recommendations, fluid and sodium management and physical ativity and recognition of deteriorating symptoms. The EHFScB is used to measure the effectiveness of education and support for HF patients. At one month, IG had higher self-care attitudes in the three dimensions of EHFScBS and observed that the mean dimensions scores of this group of patients were increasing compared to baseline. At baseline the mean dimensions score were for the dimension adhering to recommendations $\bar{x}$ = 12.3 (SD =2.3), for fluid and sodium management, $\bar{x}$ = 10.2 (SD =3.0), for physical activity and recognition of deteriorating symptoms $\bar{x}$ = 9.9 (SD=2.8) while at the first month was $\bar{x}$ = 14.2 (SD=1.4), $\bar{x}$ = 13.0 (SD=2.1) and $\bar{x}$ = 12.7 (SD=1.7), respectively. Possible explanation for this finding may be the time and the context of the intervention that started from early stage, either before the discharge of the patients or during the first meeting, and information for preventing and recognizing symptoms were given right from the beginning of the intervention. The self –care attitudes continue to be higher in the IG compared with the CG until the one year the intervention. The educational meetings were permormed every month and patients could resolve any doupts they had about HF and DM and support given to modify their lifestyle behavior. The same time patients were able and encouraged to communicate with HPs whenever they needed to.

10.6 Physical activity and Health Related Quality of Life in patients with Heart Failure and Diabetes Mellitus

At first month after the intervention, no difference in the overall physical activity was observed between the participants of the IG and the CG, except in the dimension of walking [IG 369 (245), CG 376 (286.1)] but there was an icreases trend in the IG compared with the CG between a month to six months after the intervention. There was a difference at three months, six months and one year after the intervention, when the participants in the IG had higher overall physical activity compared to the CG [3 months IG 946(493.1), CG 550.3 (230.3), 6 months IG 1,162 (641.2), CG 624.7 (242), 1-year IG 894.8 (353.9), CG 733.2 (32.7)] and specifically in the dimensions of walking and moderate exercise. In the dimension of walking, there was a statistically significant effect at three months after the intervention ($p‹0.001$), at six months ($p‹0.001$) continued up to one year ($p‹0.001$). There was also a statistically significant effect of the intervention after the three months ($p‹0.001$) and continued up to six months ($p‹0.001$) at moderate exercise of physical activity. A moderate level of physical activity on the IPAQ means that patiemts were doing some activity more than likely equivalent to half an hour of at least moderate intensity physical activity on most days (Craig et al., 2003).

The explanation of these findings was that most of the patients at the beginning of the meetings had a fear and a lack of confidence to take part in physical activity exercising. They had the fear of feeling of discomfort during exercising due to symptoms that may occur during physical activity such an acute event or dyspnea, fatique or hypoglycaemia (Alosco et al., 2015). Therefore, at the beginning the exercise sessions started with breathing exercises and beathing techniques they can use in case they experience anxiety or dyspnea. After one month, patients felt more confidence to perform physical activity. During the meetings information were given to each patient by the nurses and physiotherapist specialists, depending on the NYHA stage I-IV or stage A-D they experience, and all the patients felt willing to perform ecercise. Many of the monthly meetings took place in a park for walking and patients often required for it and enjoyed it. Before physical activity, patients were checked for their blood pressure, pulse and glucose level, especially those who receive insulin, to prevent episodes of hypoglycaemia during the exercise. Patients had sweet candies with them to face hypoglycaemia if it occurred. Physical activity for HF patients with DM is indicated in the quidelines as significant part of maintaining HR-QoL (McDonagh et al., 2021).

10.7 Diabetes Mellitus and Health Related Quality of Lfe for patients with Heart Failure

In the current study, patients in the IG had better HR-QoL compared with the CG in almost all the dimensions of the ADDQoL at three, six months and one year after the intervention with exception the dimension of working life, holidays, family life and sex life. Patients in the IG experienced better HR-QoL in the dimensions of leisure activities, journeys, physical health, friendship and social life, self-confidence, motivation, feelings about future, financial situation, living conditions, dependence on others, freedom to eat and drink anything they wanted (p ‹0.001) and DM was not found to affect their HR-QoL. An explanation is given that 33% of the patients were widowers, so they didn’t have any close personal relationship /sex life and most of them were pensioners with mean age $\bar{x} = 73.9$ (SD = 9.1) years old, so without working life. HF patients with DM may feel fear to get away for holidays because they feel safe to stay near their doctor or hospital because they fear they could not find any medical help in case they need it during holidays. During the monthly meetings, patients got the necessary knowledge and skills with motivation and enpowermnent to be able to self-manage any issue concerned DM or asking help by HPs whenever needed. The level of HbA1c showed also that the patients in the IG had significally lower values across time (one month, three months, six months and one year) compared to C.G (p ‹0.001). The levels of HbA1c from 7.1 % (0.5) at baseline falls to 6.9% (0.4) in one year and in the CG from 7.5% (0.7) at baseline falls to 7.4% (0.6) in a year. Despite the fact that the level of HbA1c for the CG was higher compared with the IG from the baseline, the level of HbA1c in the IG has a declining trend in all time points after the intervention with differences between the two groups.At baseline the level of HbA1c in the IG was 7.1 (0.5) and in the CG 7.5 (0.7), at three months in the IG was 6.9(0.4) and 7.5 (0.7) in the CG, at six months 6.9 (0.3) in the IG and 7.4 (0.7) in the CG and in a year 6.9 (0.4) in the IG and 7.4 (0.6) in the CG. An explanation of this, may be the fact that the intervention was continuous and was target on special issues regarding sugar free diet or exercising, which help to control glucose levels despite the results of the systematic review that showed DM patients give more priority to control HF symptoms and not hyperglycaemia (Philippou et al., under review). Observational studies suggest that moderate glycaemic control may be the goal for patients with DM and HF (Elder et al., 2016). Although studies consistently demonstrated a progressive increase in the risk of incident HF or HF hospitalization with rising HbA1c more than 8%, 9% or even 10%. (Blecker et al. 2016, Skrtic et al. 2017). Indeed, some studies shows that the HF event rates were higher, when HbA1c levels, fell below 6% (Skrtic et al., 2017). Elder et al. (2016) supports that the association between HbA1c and mortality among patients with HF is consistently U shaped, with the lowest mortality in patients with HbA1c 7% - 8%.

10.8 'SupportHeart' Management Program and Morbidity and Mortality of patients with Heart Failure and Diabetes Mellitus

Previous studies have shown a reduction of 50% in HF re-admissions and 20% in mortality in HF patients who were involved in HF management programs, but results are controversial (Lambrinou et al. 2012, McDonald 2014). Mortality reached 10% and 25% of patients after an acute event and patients will be readmitted within the first month after discharge (Discroll et al., 2016). Some reports support that various factors are responsible for the increased one-month readmission rates, including elevated NYHA classification and treatment with beta-blockers, loop diuretics, thiazide, or nitrates (Aizawa et al,. 2015). Bradford et al. (2016) refer that retired and/or disabled patients had one or more ER visits in the last 3 months and stay in hospital more than 5 days at discharge (Bradford et al., 2016). In the current study, acute events had lower rate in the IG. Acute events were either readmissions due to fluid overload or ER visits. In fact at the period of recruitment to one month, there were 3/65 (4.6 %) acute events in the CG and 2/56 (3.6%) in the IG. After a month and until three months time point, in the CG more acute events were observed [7/61(10.9%)] compared to the IG [3/52 (11.5%)]. After three months and until the sixth month time point, in the CG were observed more acute events [12/61(19.7%)] compared to the IG [6/52 (11.5 %)]. Between six months to one year was observed 8/58 (13.8%) acute events in the CG and no any acute event in the IG [0/49 (0.0%)]. There was no significant diferences in the mortality across the two groups (p › 0.05) at all time points and the largest different observed between three to six months after the intervention, where 3/61 (4.9%) deaths were observed in the CG and only 1/52 (1.9%) death in the IG. When considering both acute events and mortality after three months and until six-month time point, in the CG [9/58 (15.5 %)] were observed more acute events and deaths compared to the IG [1/49 (2%)] (p=0.02)].

The fact that no patient had any acute event (readmission or ER visit) at the time between 6 months to one year in the IG, perhaps was due to the close monitoring during the program and the knowledge patients had about the early recognition of decompensated symptoms. Kalogirou et al. (2020) support that important issues that a management program should contain, include the knowledge and understanding of HF, self-care, self-efficacy, family and caregiver involvement, psychosocial well-being, HPs support, and technology use. All the above components were involved in the current program for patients with HF and DM and more results are expected from the involvement of family/caregivers and smart watches usage, in the RCT program ‘SupportHeart’. The current supportive management program for HF patients with DM- part of the RCT ‘SupportHeart’- was the only programme that was running during the two years of the pandemic of COVID-19 where the communication with the patients continued through DHT (phone calls or via viber) so the patients and the members from the ‘SupportHeart’ team, could ‘see’ each other and the communication and the interaction was more effective.

10.9 Limitations of the study

The current study has some limitations that need to be considered. This study is a secondary analysis of the RCT ‘SupportHeart’ that studied patients with HF, so the randomization could not be achieved for the particular group of patients (HF patients with DM); therefore, some differences that exist between the IG and the CG at baseline are justified. None of the patients in the study had NYHA I since most of the participants recruited from hospitals and this proves that patients with NYHA I are mostly misdiagnosed and this should be considered in future studies since the ‘SupportHeart’ program can improve the HR-QoL from the early stages of the HF trajectory. This shows the need for new RCTs with a sample exclusively with patients with HF-DM considering more clinical characteristics; the duration of diabetes, the insulin or oral antihyperglycaemic therapy, the body mass index (BMI) and other clinical characteristics that may affect the HR-QoL of HF patients with DM. The study sample did not represent all patients with HF-DM due to the exclusion criteria that were set, since patients with dementia or any kind of mental illness, patients under hemodialysis and patients tranfered to nursing homes after discharge, were not included in the current study. Also patiens from rural areas where not considered to the sample. Finally, this study was based in pragmatic methodology and pragmatic trials do not most of the times have constraints on patients and clinicians; between parients and HPs from the research team created a ‘bond’ and a relationship since they focused on patients needs and was patient – centred; but this may lead to inconsistent or missing data (Sox & Lewis, 2016).

11. CONCLUSIONS

The current study is the first study that studied the HF-DM population and introduce supportive care in the management of HF patients with the comorbidity of DM. Supportive care found to be important factor for HF-DM management programs. The study was effective regarding HR-QoL, self-management, knowledge and patients’ adaptation of the knowledge as a health care behavior, perceived social support in the dimension of exercise tolerance, and morbidity and mortality for the population of HF-DM patients. The current study is a subanalysis of the ‘SupportHeart’ program, based in pragmatic methodology design, on the ‘real world’ and on the ‘real needs’ of HF patients with DM focused on a patient-centred approach that was missing from previous studies and previous management programs. Future studies should be focused on the population of HF-DM patients and access and apply supportive care management programs in a long-term duration for HF-DM population with the scope to icrease their HR-QoL, reduce acute events and make patients actively participants in the management of their chronic conditions, in a continues and long-term support.

12. THE CONTRIBUTION TO CLINICAL SETTING AND FUTURE RECOMMENDATIONS

There are no any management programs until now, for the population of HF-DM patients that applied in clinical settings. The already existing management programs applied for HF population aiming to improve the HR-QoL of HF patients and most of them are encouraging but still, the main reason of decompensation is no adherence to the therapy and lots of patients feel are not supported enough. This study that was based in pragmatic methodolgy, could be easily applied in general population, sinse it did not use specific strategy like other clinical trials, but has an individualized patient centre - approach based on each need of the patient that differs in each time point and for each patient. Therefore, there is a need for supportive, not only HF patients but also HF patients with the largest comorbidity of HF, DM through better communication and education so they can be able to manage their condition.

The Health Care Systems nowadays, have to deal with various challenges like the NHS, which was a successful and productive health care system the previous decades in UK, and is threatened nowadays and is under a huge pressure for various reasons. Therefore, a change is needed and a different approach on managing chronic diseases must prioritized. Supportive care management programs based on early support, on close and continuous follow-up, through the empowerment of the patients can empower them in actively take part to find solutions, to cope with their chronic illnesses, achieve long-term improvements in their HR-QoL, and decongest Health Care Systems. This program could be implemented in the Health Care System in Cyprus for HF patients with DM as well as for other chronic illnesses, based on a patient-centred approach. Therefore, future research is of great importance to be held in HF-DM population, evaluating the effectiveness and implementation of such supportive care management programs in this group of patients with the scope to improve their HR-QoL.

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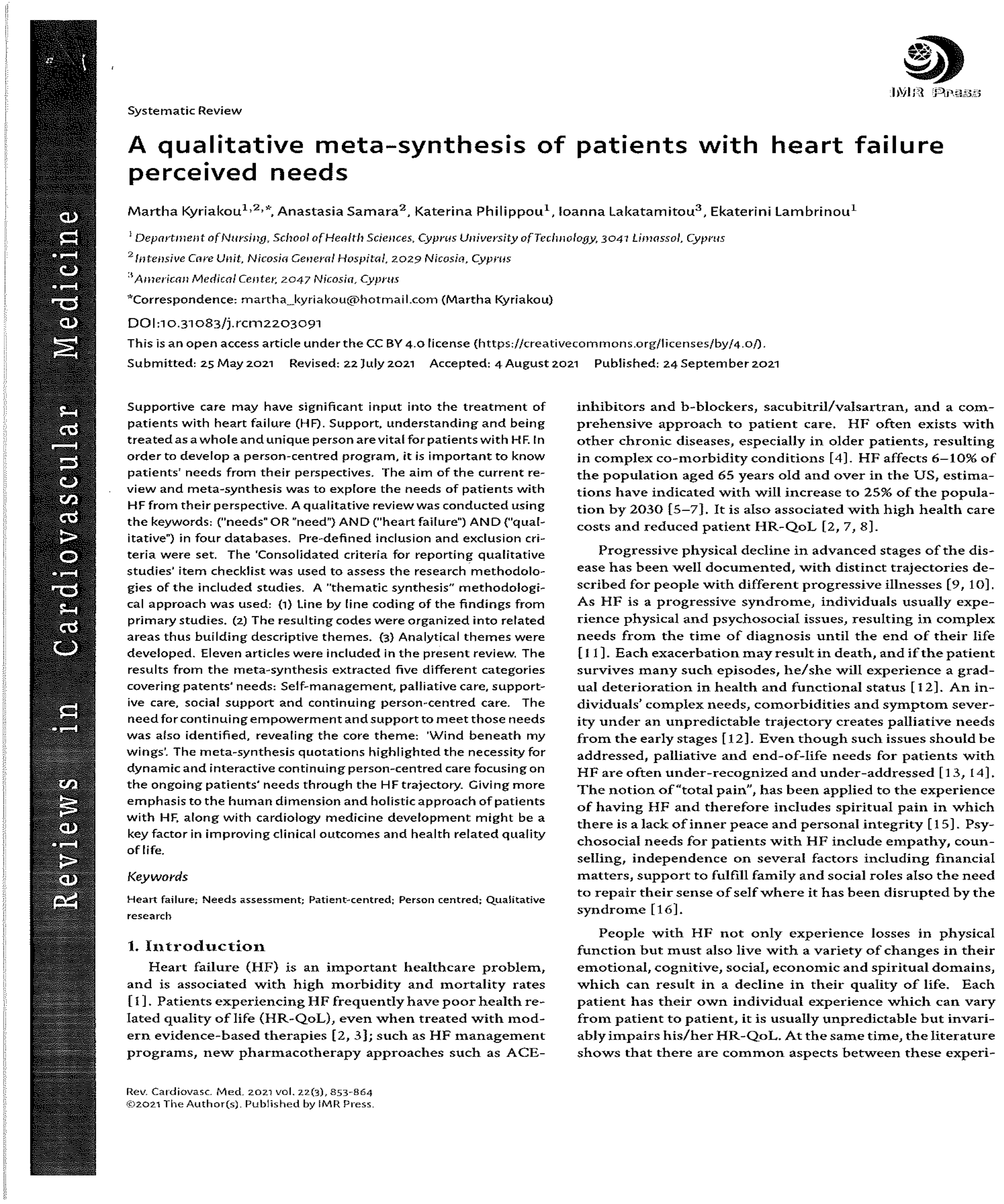
APPENDIX I

Systematic review and meta-synthesis.

'A Qualitative Meta-synthesis of Patients' with Heart Failure Perceived Needs'.



Reviews in Cardiovascular Medicine

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Systematic Review

A qualitative meta-synthesis of patients with heart failure perceived needs

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Supportive care may have significant input into the treatment of patients with heart failure (HF). Support, understanding and being treated as a whole and unique person are vital for patients with HF. In order to develop a person-centred program, it is important to know patients' needs from their perspectives. The aim of the current review and meta-synthesis was to explore the needs of patients with HF from their perspective. A qualitative review was conducted using the keywords: ("needs" OR "need") AND ("heart failure") AND ("qualitative") in four databases. Pre-defined inclusion and exclusion criteria were set. The 'Consolidated criteria for reporting qualitative studies' item checklist was used to assess the research methodologies of the included studies. A "thematic synthesis" methodological approach was used: (1) Line by line coding of the findings from primary studies. (2) The resulting codes were organized into related areas thus building descriptive themes. (3) Analytical themes were developed. Eleven articles were included in the present review. The results from the meta-synthesis extracted five different categories covering patents' needs: Self-management, palliative care, supportive care, social support and continuing person-centred care. The need for continuing empowerment and support to meet those needs was also identified, revealing the core theme: 'Wind beneath my wings'. The meta-synthesis quotations highlighted the necessity for dynamic and interactive continuing person-centred care focusing on the ongoing patients' needs through the HF trajectory. Giving more emphasis to the human dimension and holistic approach of patients with HF, along with cardiology medicine development might be a key factor in improving clinical outcomes and health related quality of life.

Keywords

Heart failure; Needs assessment; Patient-centred; Person centred; Qualitative research

1. Introduction

Heart failure (HF) is an important healthcare problem, and is associated with high morbidity and mortality rates [1]. Patients experiencing HF frequently have poor health related quality of life (HR-QoL), even when treated with modern evidence-based therapies [2, 3]; such as HF management programs, new pharmacotherapy approaches such as ACE-inhibitors and b-blockers, sacubitril/valsartran, and a comprehensive approach to patient care. HF often exists with other chronic diseases, especially in older patients, resulting in complex co-morbidity conditions [4]. HF affects 6–10% of the population aged 65 years old and over in the US, estimations have indicated with will increase to 25% of the population by 2030 [5–7]. It is also associated with high health care costs and reduced patient HR-QoL [2, 7, 8].

Progressive physical decline in advanced stages of the disease has been well documented, with distinct trajectories described for people with different progressive illnesses [9, 10]. As HF is a progressive syndrome, individuals usually experience physical and psychosocial issues, resulting in complex needs from the time of diagnosis until the end of their life [11]. Each exacerbation may result in death, and if the patient survives many such episodes, he/she will experience a gradual deterioration in health and functional status [12]. An individuals' complex needs, comorbidities and symptom severity under an unpredictable trajectory creates palliative needs from the early stages [12]. Even though such issues should be addressed, palliative and end-of-life needs for patients with HF are often under-recognized and under-addressed [13, 14]. The notion of "total pain", has been applied to the experience of having HF and therefore includes spiritual pain in which there is a lack of inner peace and personal integrity [15]. Psychosocial needs for patients with HF include empathy, counselling, independence on several factors including financial matters, support to fulfill family and social roles also the need to repair their sense of self where it has been disrupted by the syndrome [16].

People with HF not only experience losses in physical function but must also live with a variety of changes in their emotional, cognitive, social, economic and spiritual domains, which can result in a decline in their quality of life. Each patient has their own individual experience which can vary from patient to patient, it is usually unpredictable but invariably impairs his/her HR-QoL. At the same time, the literature shows that there are common aspects between these experi-

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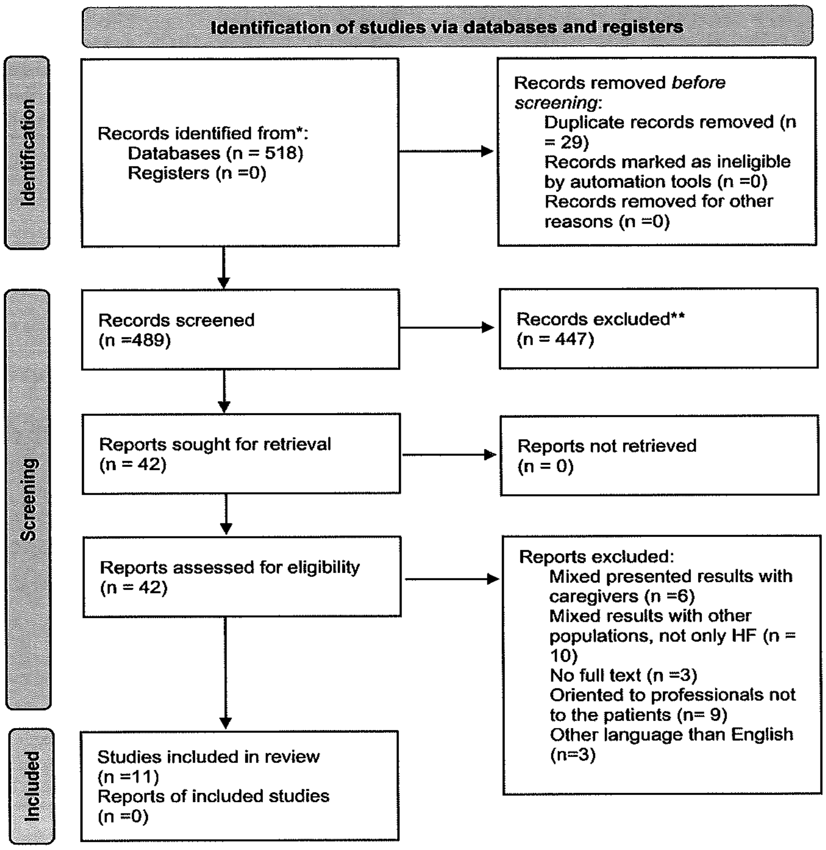

Fig. 1. Flowchart of the included studies.

*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers).

**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hofmann TC, Mulrow CD, *et al.* The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. British Medical Journal. 2021; 372: n71.

For more information, visit: http://www.prisma-statement.orq/.

ences [17]. Even though evidence exists for successful management programs that improve HF-related outcomes [18, 19], including readmission rates [20], testimonies from patients may show differing results (qualitative studies). Qualitative studies have already been carried out to explore the needs of patients with HF [4, 16, 21–28]. What is lacking in the literature, to date, is a summary of those needs which are related to topics in order to develop a comprehensive overview of patient needs, thus affording the opportunity to design a person-centred approach to care provision. A qualitative meta-synthesis provides the opportunity to intergrade and synthesize the literature published to date, thus guiding clinical practice and future research. In addition, the results of a meta-synthesis can help health professionals (HP) develop interventions focusing on the patient's true needs and expectations whilst also enabling then to detect vital aspects of the patient experiences that are currently not being addressed.

In order to develop a person-centred program, it is important to know what patients' needs are based on their own perspectives. This will contribute towards developing person-centred management programs. For people with HF, support, understanding, receiving comfort, and being treated as a whole and unique person are vital [23, 29]. These could be offered to a patient through supportive care as the "care that helps the patient and people important to them to cope with life-limiting illness and its treatment — from before diagnosis, through diagnosis and treatment, to cure or continuing illness, or death and bereavement" [30], which aims to improve their HR-QoL [31]. The aim of the current review and meta-synthesis was to identify the needs identified by patients with HF.

2. Methods

A literature review was conducted using a qualitative methodology. Zimmer *et al.*, (2006) [32] stated that meta-synthesis involves the process of comparing, translating and analyzing the original results that leads to the generation of the new interpretations. Initially, a systematic review of the literature was conducted. Two researchers undertook the searches using the keywords: ("needs" OR "need") AND ("heart failure") AND ("qualitative") in the PubMed, CINAHL, PsycoINFO, and EBSCO databases, with outputs published prior to, and including, December 2019. The researchers screened the titles of the articles retrieved and identified the potentially relevant publications. The eligibility of the relevant abstracts was examined separately by the two authors, who both reviewed all abstracts. The two authors used standard pretest selection forms, independently, to assess eligibility. A third author was involved to reach consensus when necessary.

The inclusion criteria for the selection of the articles were standardized. Articles needed to use qualitative methodology involving patients with HF, and have explored patient needs from a patient perspective. Articles had to be published in the English language. Articles involving carers/caregivers were included in the review only where the patient results were presented separately. Exclusion criteria were defined as: articles including populations other than patients with HF or articles not presenting results for patients with HF separately, articles focusing on the patients' experience or perspectives generally related to HF but not related to their needs, and studies exploring caregivers and/or family needs. The search yielded 518 articles from which 29 duplicates removed, a further 447 papers were excluded after the titles and abstracts of the articles had been reviewed. The remaining 42 articles were assessed for full eligibility, and 11 publications were found to fulfill the inclusion criteria and were therefore included in the systematic review and meta-analysis (Fig. 1). The main figures pertaining to the studies included are summarized in Table 1 (Ref. [4, 16, 21–28, 33]).

The methodological quality of the included articles was assessed using the 'Consolidated criteria for reporting qualitative studies' (COREQ) item checklist (**Supplementary Tables 1,2**) [34]. This was conducted in order to gain an overview of the methodological quality of the studies included. No study was rejected due to low methodological quality. The checklist consists of 32 specific items for reporting qualitative studies and includes generic criteria that are applicable to all types of research reports. The criteria included support researchers to report upon important aspects of the research team, study methods, context of the study, findings, analysis and interpretations. The methodological assessment of the included studies is shown in **Supplementary Tables 1,2.**

In order to verify the validity of the interpretation within the texts, a "thematic synthesis" methodology was used to undertake the current meta-synthesis [35]. This method is a three-step process: (1) Free line by line coding of the findings of the primary studies. (2) Free codes extracted were then organized into related areas to build descriptive themes. (3) Analytical themes were developed [35, 36]. The first step, line by line coding of primary results, was conducted independently by five researchers. Researchers gave one code in each initial patient quote. The resulting descriptive themes, with a representative initial quote, are presented in Table 2 (Ref. [4, 16, 21–28, 34]). Additional information for all quotes from the primary studies, and their assigned codes, are presented in **Supplementary Table 3**.

In the next step, "new" codes were created to capture the meaning of the groups from the initial codes. This step of the methodology enabled the codes produced to be comparable. A draft summary of the findings organized by the descriptive themes produced was written by one of the researchers, then reviewed and revised by all of the researchers. Then, the researchers worked together to capture all of the linkages between the themes produced. A "map" was created, as shown in Fig. 2, with two themes and five sub-themes, to enable development of the final model. The researchers located similarities, then proceeded to group the codes into descriptive themes.

The final stage consisted of the researchers going beyond the systematic synthesis of primary studies, by interpreting the findings and results in a critical way. They started thinking the descriptive themes produced, first independently and thereafter as a group, which concluded in merging of the themes, which concluded with the production of five "new" themes. The "new" themes were created to combine similar needs which had emerged from the meta-synthesis. For instance, palliative care was the umbrella term for: pain relief, symptom relief and end of life care. This 'new' term/theme was created to cover all three themes. In this last step, the fi-

Table 1. Articles included in the meta-synthesis.

Author (Year) Country	Aim	Participants	Main findings
Cortis and William (2007) UK [21]	To explore the experiences of older adults with CHF and gain a deeper understanding of their palliative and supportive needs and the value of possible interventions.	N = 10 50% males Years of age (range) 80–90 yrs old NYHA class: II–IV	Four main themes: 1. Experiences of living with heart failure a. Symptoms b. Loss of independence c. Physical, psychological and social isolation d. Loss of self-esteem and self-worth 2. Ways of coping a. Stoicism and acceptance b. Perception of heart failure 3. Constraints to coping a. Not being a burden b. Expectations of care 4. Developing resources for coping a. Self-help and adaptation b. Seeking reassurance
Harding *et al.* (2008) UK [22]	To generate recommendations for information to CHF patients and their family carers, in line with UK and International policy guidelines.	N = 20 80% males $\tilde{x}$ age =69 70% NYHA III LVEF mean 34% ± 8.33%	Five main themes: 1. CHF symptoms and management 2. Disease progression and future care 3. Living with inadequate information 4. Barriers to effective information provision 5. Recommendations to improve information provision.
Bekelman *et al.*, (2011) [33]	To learn about patients' and their family caregivers' major concerns and needs and to explore whether and how palliative care would be useful to them.	N = 33 (10F/23M) $\tilde{x}$ age = 59 yrs NYHA II–IV EF mean = 31%	Six main themes: 1. Major concerns and needs 2. Physical aspects of care 3. Psychological and psychiatric aspects of care 4. Social aspects of care 5. Future of illness 6. Structure and processes of care
Andersson *et al.* (2012) SE [23]	To describe how people with HF experience support in Swedish primary healthcare.	N = 11 participants (6F/5M) $\tilde{x}$ age = 77 yrs old	Four main themes: 1. Being abandoned 2. Lack of information 3. An absent dialogue 4. To develop strategies on one's own
Gerlich *et al.* (2012) DE [24]	To explore the needs and experiences of older patients with advanced HF in Germany.	N = 12 participants 50% males $\tilde{x}$ age = 84.5 yrs old	Three main themes: 1. Understanding of illness and prognosis a. Information needs b. Source of information c. Dealing with prognosis 2. Health care services a. Hospitals b. In the community c. Finances 3. Social life a. Social activities b. Communication about illness with family, friends and neighbours.
Baudendistel *et al.* (2015) DE [28]	To explore patient perspectives on guided treatment of HF across multiple health care sectors.	N = 17 participants (5F/12M) $\tilde{x}$ age = 71.5 yrs old (EF >35%)	Five main themes: 1. Quality of health care in general 2. initial evaluation – establishment of diagnosis 3. Treatment and professional advice 4. Follow-up 5. Coordination of care
Klindtworth *et al.* (2015) Germany [4]	To understand how old and very old patients perceive advanced heart failure and to assess their medical, psychosocial and information needs at the end of life.	N = 25 participants $\tilde{x}$ age = 85 yrs old (14F/11M) (NYHA III/IV)	Two main themes: A. Patient understanding of disease and prognosis 1. Dealing with advanced heart failure and ageing a. Perception of heart failure b. Adaption to changing conditions

Table 1. Continued.

Author (Year) Country	Aim	Participants	Main findings
			c. Appraisal of quality of life d. Information regarding life 2. Dealing with the end of life a. Value and worthlessness in old age b. Preparation for death B. Delivery of health 1. Perceptions regarding care a. Appropriateness of medical care b. Continuity of care 2. Interpersonal relations a. Interaction in the process of care b. Specific aspects in physician-patient interaction 3. Meaning of family
Ross *et al.* (2015) UK [27]	To identify the spiritual needs and spiritual support preferences of end-stage heart failure patients/carers and to develop spiritual support guidelines locally.	N = 16 participants (7F/9M) $\bar{x}$ age = 73 yrs old NYHA IV	Two main themes: 1. Experience of healthcare and effects of the illness a. Love and belonging b. Hope and coping c. Meaning and purpose d. Faith, believe and existential issues 2. Spiritual help/support a. Home visiting service and telephone access b. Care-coordinator c. Voluntary Organisations d. Supporting carers
Yu *et al.* (2016) CN [26]	To explore the underlying perceptions of information needs from the HF patients themselves.	N = 26 (11F/15M) $\bar{x}$ age = 58.62 yrs old NYHA II–IV	Five main themes: 1. Living with inadequate information a. Poor understanding of HF b. Inadequate knowledge of medication c. Uncertainty about coping strategies 2. Content of information needs a. Risk factors b. Medication c. Disease management strategies 3. Motivators for information learning a. Desire to improve their current health condition b. Obligations towards other family members c. Maintaining hope for the future 4. Barriers to information acquisition a. Economic concerns b. Geographical inconvenience c. Material-related and patient-related factors d. Little communication with health professionals 5. Preference for information deliver a. Direct communication with health professionals b. Written materials c. The internet d. TV programs e. Newspaper
Kristiansen *et al.* (2017) DK [25]	To identify the learning needs of patients with HF and ascertain what they emphasize as being important in the design of an educational website for them.	N = 16 (4F/12M) Years of age (range) 47–78 yrs old	Four main themes: 1. Learning needs experienced by patients between follow-up visits 2. Anxiety and uncertainty as driving forces for learning 3. Managing my condition 4. Managing my daily life

Table 1. Continued.

Author (Year) Country	Aim	Participants	Main findings
Namukwaya *et al.* (2017) UG [16]	To describe patients' experiences of their illness, their perspectives of their multidimensional needs and what they and their HPs want to be improved.	N = 21 71.4% females Years of age (range) 18–70 yrs old	Five main themes: 5. Physical needs a. Need to control symptoms and for cure 6. Information needs 7. Psychological needs a. Need for reassurance b. Need for empathy c. Need for attaining life goals and live a normal life d. Need for counseling and emotional support 8. Spiritual needs a. Need to maintain hope b. Need to find the meaning of their illness and for spiritual support c. Need to re-establish a sense of purpose d. Need to feel cared for and to be treated with respect 9. Social needs a. Need for independence and for having control b. Need for practical help and companionship c. Need to fulfill family and social roles

nal themes were developed covering all topics related to the needs of patients with HF, as identified by the patients themselves. The final themes produced were: continuing person-centred care, social support, supportive care, palliative care and self-care management. In addition, all of the discussions between the researchers revealed the need for continuing support of the patients in order to be able to cope with the needs arising throughout the HF trajectory; and that is how the core theme 'Wind beneath my wings' arose (Fig. 3).

3. Results

From the systematic review eleven studies were assessed as eligible and were included in the present review and meta-synthesis. Through the three-step process of the thematic synthesis one core theme (namely 'Wind beneath my wings'), and five main themes were revealed: continuing person-centred care, social support, supportive care, palliative care and self-care management. A description and relevance of the core theme, and each of the main themes, is listed below.

3.1 Core theme: wind beneath my wings

Researchers identified the mechanisms to meet patient needs, extracted from the literature review and meta-synthesis, that covers continuing empowerment and support illustrated by the core theme: 'Wind beneath my wings'. The results also showed five different categories to cover patents' needs, which interacted with each other: Self-management, palliative care, supportive care, social support and continuing person-centred care (CPCC).

"[...] I would like to know, what the problem is. I would like to know, what treatment I need which one I should emphasize" [16].

All themes are correlated between each other as shown in Fig. 3, starting from the self-care management and ending up with a continuing process, with the patient in the centre.

3.2 Main themes

3.2.1 Self-care management

Self-care is the cornerstone of HF management. Self-care comprises of adherence to behaviors, such as maintaining a low sodium diet and medication regimen, as well as symptom monitoring (self-care maintenance) to maintain physiological stability and response to symptoms when they occur (self-care management) [37].

"[...] How to protect myself and avoid risk factors [...] As long as I have ways to obtain the information, I hope I can get as much information as I can" [22].

3.2.2 Palliative care

Palliative care for patients with HF has a dual role by both treating symptoms and ensuring that patients' treatment plans match their values and goals [38, 39]. According to WHO [30] palliative care provides care in the relief of pain and other distressing symptoms; affirms life, and regards dying as a normal process; intends neither to hasten nor postpone death and offers a support system to help patients live as actively as possible until they die. This holistic approach also addresses the psychological and spiritual aspects of patient care and supports families and informal careers during the illness and into bereavement.

"This made me feel sick, uncomfortable. If you see what ...Is this your last hour? [...]" [24].

3.2.3 Supportive care

Supportive care is necessary throughout the HF trajectory in order to manage physical and psychosocial issues, and comorbidities, to preserve or improve QoL for patients and

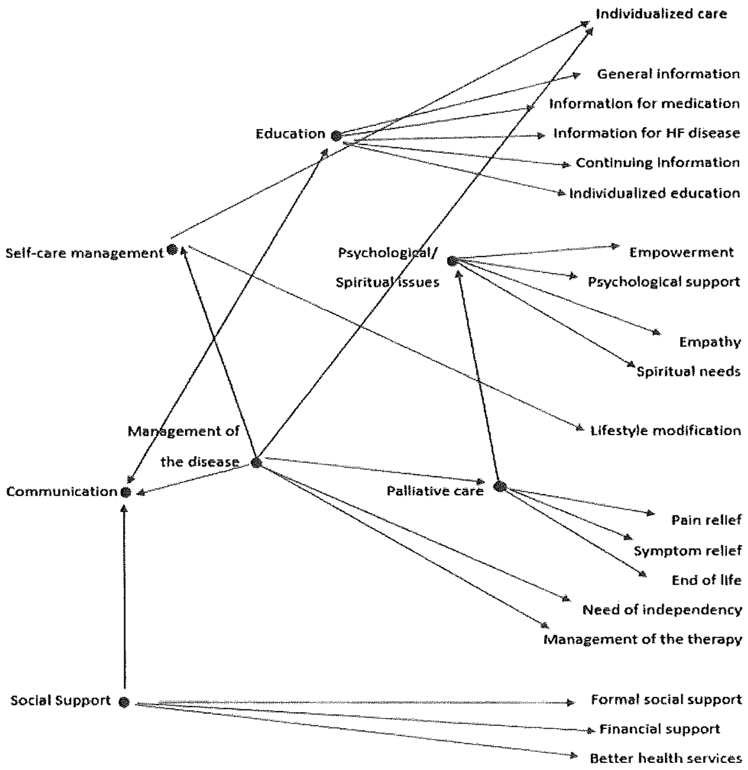

Fig. 2. Second step of the meta-synthesis: free codes extracted with all possible linkages between the themes.

their families [38]. Supportive care should be responsive in changing patient's needs, especially during times of increased vulnerability, such as after hospital discharge. Supportive care in HF comprises of four different components; communication, education, symptom management, and psychological and spiritual issues [40]. Thus, the four above components created the "new" theme entitled 'supportive care'.

"[...] it's good when you have someone who looks after you [...] I do not want too much care [...] too much responsibility" [4].

Supportive care is "the care that helps the person and people important to them to cope with life-limiting illness and its treatment—from before diagnosis, through diagnosis and treatment, to cure or continuing illness, or death and bereavement" [40].

3.2.4 Social support

Social support is a multi-faced concept that positively influences disease-related outcomes in multiple chronic illnesses, including HF [41, 42].

"I don't meet people [...] very very lonely. Very very lonely" [23].

"I am worried I do not have someone to live with. I live here alone no one even to make me a cup of tea" [16].

Four types of social support have been found to influence disease-related outcomes in patients with HF, including emotional support, instrumental/tangible support, informational support, and appraisal support [42]. Social support distinguishes between informal and formal. The former refers to family members, friends, neighbors, and others, while the latter refers to professionals/public services [43].

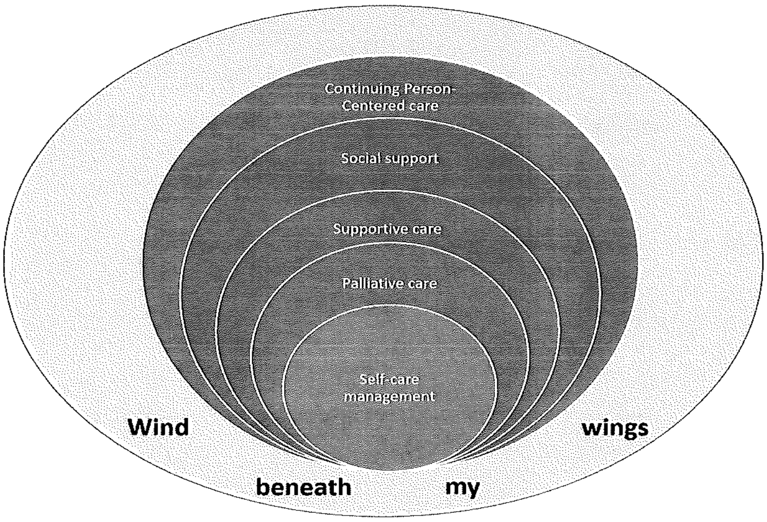

Fig. 3. Final themes covering all topics related to patients with heart failure needs.

3.2.5 Continuing person-centred care

CPCC is advocated nowadays as a key component of effective illness management [44, 45]. Giving the patient the opportunity to introduce her/himself as a person in the form of an illness narrative is the starting point in creating a collaborative, egalitarian provider-patient partnership that encourages and empowers patients to actively take part in finding solutions to their problems [44].

"No, no, nothing about that at all. Just this great stream of medicines, between puffs and pills." [18].

"I suppose they do (explain symptoms) but it hasn't penetrated." [18].

"What they explain (to) me, I forget." [18].

"[...] But who is going to explain it to me so that I understand? I haven't met anyone yet who can do that." [20].

4. Discussion

This meta-synthesis provides an illustration of some of the needs that occur in the lives of patients with HF. The main themes, discovered from the results, covered patients' needs depended upon fluctuations occurring in the illness trajectory, patients' functional status and illness severity [38]. Although these revealed themes have already been reported in previous studies as important aspects in HF management, the new input highlighted here is that they come directly from patients with HF themselves, and the challenge is now to find mechanisms to respond to them in an ongoing process.

The current meta-synthesis provides information focusing in two aspects of HF management. Firstly, the important active role of the patient being the protagonist in dealing with his/her illness, and secondly the results highlighted that the actions of all the mechanisms of disease control needed to reach the patient with HF and his/her needs.

Either way, the results remain the same, health care professionals (HPs) should consider all of these aspects, and in collaboration with the patient find ways of addressing their specific needs. Each person is unique and has a different perception of his/her life, even when experiencing similar situations of uncertainty and restriction with others [45]. Thus, the key solution remains person-centred care. Ekman *et al.* (2011) [44] refers to giving the person the opportunity to present her/himself as a person in the form of an illness narrative as a starting point for building a collaborative, egalitarian provider (care and treatment expert)-patient (person expert) partnership that encourages and empowers persons to actively take part in finding solutions to their problems. "Wind beneath my wings" is the role of the HPs (the wind), who encourage patients (the wings) to take part in their care, to control and take decisions for their own health and HR-QoL. Patient empowerment helps increase patient awareness as well as encouraging mutual trust and open communication between patients and HPs [46]. Following HF patients in a closer manner, checking limitations and ensuring that changes which frequently occur are identified, especially in

Table 2. Developed of themes.

Codes	Description	Illustrative quotes
Individualized care	Patients asking for care based on each conditions, abilities, needs, routines, and goals	"[...] Let them take time to know from the patient what they need" [16] " [...] it is giving a certain kind of orientation to you [...] things run fairly straight or if you to let things slide" [28]
General information	Patients asking information for all aspects	"The most important thing is to also let the patient know what is going on [...]" [16] "[...] I know nothing about my disease [...] and medications were just given to me" [23]
Information for medication	Patients asking information regarding medication	"I think if you don't really know about them (medication) you'll stop taking them" [21] "[...] you get too little information [...] what effects they have." [25]
Information for HF disease	Patients asking information regarding HF	"I have no knowledge of HF [...] I think it is more serious...I cannot describe it [HF] clearly...I really don't know" [26] "I did not know I had it [...] I was almost shocked" [23]
Continuing education	Patients seeking resources of information related to HF	"I need a website where I can search for different symptoms and someone to talk to." [25] "[...] it could be like a space for patients' opinions or experiences" [25]
Individualized education	Patients asking for education depending the need of each one, their preferences and special abilities	"I'd like them to explain more in English to me exactly the reason why this isn't working, that isn't working... reasons for and why they are giving me that particular tablet" [22] "[...] I have presbyopia [...] I cannot understand [the written materials] if the materials [...] the materials should be easy to understand" [26] "[...] I would like to know, what the problem is. I would like to know, what treatment I need which one I should emphasise" (Patient 8, Interview 1) [16]
Communication	Patients asking to communicate better with health professionals	"A simple conversation with the doctor. So, everything is explained to me, what it is all about and what is going on" [28] "I think direct communication with health professionals is better [...] health professionals are always very busy" [26]
Empowerment	Patients asking to support them providing them with what they need to keep going	"I needed somebody to build me back up" [27] "[...] now I have to plan much more [...] so I find it hard [...] you need to go somewhere where you can rest" [25] "[...] People need some kind of counselling" [33]
Psychological support	Patients asking for support regarding psychological issues	"[...] And you start panicking and it starts mucking up your sleep [...] play on your mind psychologically" [22]
Empathy	Patients asking someone to understand their emotions and imagine what someone else might be thinking or feeling	"The other thing is that they should also put themselves (the HPs) in the position of the patient especially when they are talking to them [...]" [16] "[...] Some health care workers are rude, or tough, but this should be changed they HPs should also put themselves in the shoes of the patient especially when they are talking to them" [16] "[...] Most of the (providers) are just there for the medical part. They are not there to ask how you are really doing." [33]
Spiritual needs	Patients seeking support regarding deep feelings and beliefs of a religious nature	"[...] So when I felt overburdened I said to myself if He says 'I am the way the Truth and life and whoever knows this will be set free' so I decided to be saved [...]" [16] "But I was, well, a bit frightened [...] "Oh my God! What will still be there and remain when you are dead and gone?" [...] everything is on order [...] that reassures me now" [4]
Need for independence	Patients express the need to be independent regarding daily tasks	"Having to depend on others, that's my greatest fear. I never want that to happen, but it will happen" [24] "That is my family, they are young. I cannot even wash for them or cook for them when I want to, that is how it is with this disease [...]" [16]
Management of therapy	Patients seeking ways to manage with all actions related to the therapy	" [...] I have to hold back. The heart somehow says: "Stop, don't overdo it [...]" [4] "[...] They stop me from walking or running properly, which is actually worse than the shortness of breath" [4] "[...] I think it's more than being able to deal with one specific symptom. The hardest part is to understand you are going to deal with them all" [33]
Formal social support	Patients seek to be surrounded with people (family, friends, services) to support them	"Well, for me my GP is a central person. [...] if I had another illness, where I do need a specialist, the GP is still, at least for me, he is still the key person" [28] "There is one health care worker [...] So it is not good, they need to be trained" [16]
Financial support	Patients seeking for financial resources/support	"[...] this illness started it is a problem so I stopped working [...] I would like to eat but the financial situation does not allow me" [16] "My biggest problem is poverty [...]" [16]

Table 2. Continued.

Codes	Description	Illustrative quotes
Better health services	Patients asking for more organized and easy access to healthcare services	"[...] I live in a place which is not so developed [...] we can only get the information from the newspaper or TV, the resources are too limited anyway." [26] "It is very difficult to get in contact with care professionals in primary and hospital care" [23]
Lifestyle modification	Patients seeking help for altering long-term habits.	" [...] Well, for me it was a challenge on acting more relaxed and doing less. In the past I did very much walking with my wife for hours ... this is missing now completely [...]" [28] "[...] I am living not only for myself, but also for others [...] I should give up my bad habit of smoking [...] I need to learn more information, the more the better, to effectively control it." [26]
Pain relief	Patients asking for analgesia and be free of pain	"I only want to feel better [...] nothing good [...] I don't need anything, I can be quite alone. Pain everywhere" [4]
Symptom relief	Patients describe symptoms of heart failure and seeking for help to be relief	"[...] "You must absolutely do this" [...] I have often wished that just close my eyes and the suffering would come to an end [...] It's as someone had put a rope around your neck and is choking you [...] I was gasping for air and could not breathe" [4] "make each day count [...] live with as little suffering as possible" [26]
End of life	Patients seeking for support and care in the end of life taking into consideration their preferences	"This made me feel sick, uncomfortable. If you see what ...Is this your last hour? [...]" [28] "[...] let it be. My family knows exactly how I think and that's the way it is" [4]

an unpredictable syndrome as HF, is valuable [17]. One of nurses' priorities is to get to know the patient and how this patient copes with the syndrome [45, 47].

It is important that HPs place the patient with HF at the centre of every care effort and help him/her to address his/her unmet needs, thus achieving the best possible HR-QoL [44]. Kane *et al.* (2015) [17] refer to CPCC as the answer to the management challenges for HF, by incorporating patient preferences, values, beliefs, illness understanding, illness experience and information needs. All of the above are considered within the decision-making processes, encouraging patient engagement and collaborative goal setting. But is this enough to address the unmet needs of HF patients?

The answer is CPCC in the context of supportive care. Supportive care could be developed and provided starting from a CPCC perspective. The concept of CPCC integrates patient and family preferences and needs into the goals of care, manages symptoms to the level of comfort desired, and attempts to reduce the burden of illness on both the patients and their families [48]. In order to undertake this, HPs should extrapolate the unmet needs of each patient with HF via ongoing processes, as the needs change rapidly depending on the trajectory of the illness [9]. Therefore before providing supportive care, it is necessary for HPs to assess patient's needs and develop a concrete and consistent process that regularly monitors patients' with HF needs [44]. Supportive care is multidisciplinary holistic care provided for the patient and their family alongside the medical treatment(s), from the time of diagnosis aiming to prolong life and improve HR-QoL, and continues through into end of life care [49].

Even though a lot of successful management programs and therapies have been developed for HF patients, evidence show that people with HF frequently lack HR-QoL [20], and do not always feel that HPs respond to their needs [44]. Continuous supportive care throughout the illness trajectory may change the perception of the care provided.

5. Conclusions

The meta-synthesis quotations constitute the need for a CPCC model in patients with HF, that focuses on the ongoing needs of the individual and adapt as the needs change according to the passage of time, the evolution of his/her syndrome, their socio-economic factors [50], their environment, abilities, family and friends environment [51], the country's health care system, the technology and the possibilities of its application in everyday life and in chronic diseases [52], in short it is the general supportive care of a patient with HF across its entire spectrum and range of expressions [33].

More investigation and research is necessary to document the appropriateness of this care model, and the possible implications for all parties in HF care such as patients with HF, their families, medical doctors and other HPs, the community and state parties.

6. Strengths and limitations of this study

Our meta-synthesis has certain limitations. Following completion of the literature review, the studies which were included were qualitative studies with limited numbers of participants, cumulatively from all 11 studies, 190 patients with HF were involved. It is understandable that the number of patients cannot be considered as representative of all patients with HF. However, this meta-synthesis examined prospects, views and thoughts of patients with HF, and is the first study to do this within this specific population.

The strength of this meta-synthesis is that the meta-synthesis team comprised of qualified cardiology and HF advanced nurses and a practicing physiotherapist, all dedicated to caring for patients with HF throughout the entire disease trajectory.

7. Implication to practice

This review gives valuable information for what patients really need. The results may contribute to further develop management programs for HF patients, which become more effective in terms of clinical outcomes including adherence to therapies, acute events, HR-QoL, perceived care, and rehospitalization.

The use of supportive care in a CPCC management program, may tackle obstacles in patient non-adherence and bad communication with HPs.

8. What's new?

- The present systematic review and meta-synthesis of qualitative studies explored the needs from the perspectives of people with heart failure. Those needs have been collected into groups which reveal the main themes identified from the meta-synthesis. All needs seem to be present throughout the entire trajectory of HF, and interact with each other in a way that they all need to be addressed and not avoided. The outcomes show it is important to cope with all needs via continuing support.
- Recognizing the need for continuing support of persons with HF emphasizes new implications in practice. It highlights the dynamic relationships people with heart failure have with health professionals. Often, it is necessary to introduce new behaviors to people with heart failure (e.g., self-management, exercise, adherence to the therapy). And very often health professionals fail to establish this. A possible reason for this is that people with heart failure need continuing support to make all of the necessary changes and to cope with the needs they describe. If this information is taken into consideration, the focus in management of patients' with HF needs is having the people with HF at the centre of the care system, and continuously supporting them to establish all of the aims of care.

Author contributions

MK and EL designed the research study. All authors contributed towards analyzing the data (EL, MK, KP, AS, IL), and AS, KP and IL wrote the methodological assessment and the results of the manuscript. MK and EL wrote the rest of the manuscript. All authors read, made changes and approved the final version of the manuscript.

Ethics approval and consent to participate

Not applicable.

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Conflict of interest

The authors declare no conflict of interest.

Supplementary material

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APPENDIX II

'Adherence to the therapy of patients with Heart Failure and Diabetes Mellitus: a systematic review'.

Katerina Philippou, Martha Kyriakou, Andreas Charalambous, Nicos Middleton, Vasilios Raftopoulos, Ekaterini Lambrinou.

Abstract: A comorbidity like diabetes mellitus (DM) complicates heart failure (HF) self-care management and adherence to the therapy and results poorer clinical outcomes. This study aims to examine the various factors influencing adherence to the therapy of patients with HF and DM. A systematic literature search was established in the electronic data basis PubMed, Cochrane Library and CINAHL using inclusion and exclusion criteria.The search yielded eight articles. The introduction of empowerment models in the management of patients with HF and DM made patients more involved in their self-care management and their self-monitoring behavior and adherence were increased. Patients with HF and DM during their hospitalization, were less likely to receive smoking cessation counseling and blood pressure control and experienced longer length of stay. Patients with HF preserved ejection fraction (HFpEF) and DM were less likely to receive an angiotensin convertive enzyme (ACE) inhibitor or angiotensin receptor or beta-blockers and had worse blood pressure (BP) control compared with patients with reduced ejection fraction (HFrEF) and DM. Effective self-care management of patients with HF and DM seems to depend on the type and the severity of comorbid conditions and the availability of effective therapies. Adequate support to patients with HF and DM from health professionals (HPs) is important, to establish self-management and adherence to the therapy.

Keywords: adherence to therapy, comorbidity, diabetes mellitus, heart failure

INTRODUCTION

Previous reviews showed only 50% of persons suffering from chronic diseases adhere to the recommended therapy [1, 2]. Adherence to the therapy refers not only to the proper behavior on taking medications, but also to the patient following a proper diet, exercise and lifestyle changes [3].

HF and DM are strongly linked [4]. The relationship between HF and DM represents more than just a comorbidity. Each of these two conditions increases the risk for the onset of the other one and has a poorer prognosis than with either disease alone [5]. Almost half of patients with HF develop DM as a comorbidity [6, 7, 8]. A comorbidity like DM complicates HF self-care management and makes adherence to the therapy less possible [9, 10, 11]. These patients are at greatest risk for rehospitalizations due to complex problems such as fluid overload, insufficient and glycemic control that could be avoided or prevented, with better self-care management [12, 13, 14]. HF when exists with DM requires a complex self-care recommended therapy [11, 15, 16]. Currently, 32-51% of the hospitalized patients with coronavirus disease (COVID-19) was sufferring from DM and cardiovascular diseases (CVD). So, is of significant importance for patients with HF and DM to manage their health status the best possible way and adhere to the recommended therapy [17, 18]. Even though self-care management strategies are the key to reduce HF hospitalizations by educating patients on how to manage and monitor HF symptoms and their comorbid conditions at home, not many patients are found to have the opportunity for counselling and education [19].

A special focus is given to the comorbidities of HF and clinical recommendations on the pharmacological therapy of HF and DM [21]. Patients’ adherence and self-care management can be improved through health education and support [10, 11, 20, 21, 22]. Seems that current management programs are not effective on patients with comorbidities such as HF and DM [23, 24]. The aim of the study was to systematically review the factors influencing adherence to the therapy of patients with HF and DM.

METHODOLOGY

Study Design

Electronic data basis PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Cochrane Library were used to find studies for the particular topic. The key words used were ‘adherence to therapy’, ‘heart failure’, ‘diabetes mellitus’, ‘comorbidity’, in different combinations using the word ‘AND’. The tool ‘similar articles’ of PubMed was also used.

Inclusion and exclusion criteria were predefined. Inclusion criteria were studies published in English language until the end of August 2023 evaluating factors influencing adherence to the therapy of patients with the comorbidity of HF and DM. Exclusion criteria were studies that included populations with other CVD than HF, such as hypertension or coronary disease, populations with other comorbidities than of HF and DM, unpublished studies, pilot studies and studies of which the population was children. At first, two of the authors (KP and MK) separately searched the electronic basis, screened the titles of the articles found and selected the potentially appropriate ones. Then, the eligibility of the appropriate article abstracts was assessed by reading the abstract of reviewing relevant titles. The whole procedure included full consensus, after detailed assessment of full text documents and the input of a third author (EL) whenever a query was raised.

Quality Assessment

Two authors (KP and EL) assessed the methodological quality of the included studies. The studies were assessed using the Effective Public Health Practice Project (EPHPP) quality assessment tool for quantitative studies [25, 26].

RESULTS

Current search yielded 987 articles. Finally, eight articles were used for the current systematic review [7, 12, 24, 27, 28, 29, 30, 31]. The study selection is shown in Figure 1.

Overview of The Studies

From the eight studies included in the current systematic review, five originated from the USA [7, 12, 24, 29, 30], one study was established in Italy [27], one in Germany [28] and one in Brazil [31]. All studies used quantitative methodological approach. Details of the results of the included studies are displayed in Table 1.

Methodological Quality Assessment

The eight studies were assessed to find the degree to which the selected quantitative studies follow the quality features of selection bias, study design, confounders, blinding, data collection methods, withdrawals and drop-outs, intervention integrity and analyses. The EPHPP quality assessment [25] yielded 'strong' ratings for 2 /8 [12, 30], 'moderate' ratings for 3/8 [24, 27, 31] and 'weak' ratings for 3/8 [7, 28, 29] of the eight studies selected for the current review. More details on the rating of each study are shown in Table 2.

Adhererence, Health Care System and Therapy Related Factors

Patients with HF and DM were less likely to receive smoking cessation counseling (OR 0.89, 95% CI 0.81-0.98) and blood pressure control (OR 0.81, 95% CI 0.78-0.84) and to attain the all-or-none composite measure (OR 0.96, 95% CI 0.93-0.99) during their hospitalization [29]. In addition, health professionals' (HPs), found it difficult to apply measures in patients with HF, with or without DM and control their optimal blood pressure [7].

Patients with DM were more likely to receive an aldosterone antagonist for reduced left ventricular ejection fraction (OR 1.05, 95% CI 1.00-1.11), lipid-lowering agent (OR 1.33, 95% CI 1.26-1.41), and influenza vaccination (OR 1.05, 95% CI 1.01-1.09) [29]. The percentage of HF patients with DM that received b-blocker therapy and angiotensin converting enzyme inhibitor/angiotensin receptor blocker (ACEi/ARB) at the 60-to 90 –day follow up period was higher than that between HF patients without DM [8]. Patients with DM and HF with preserved ejection fraction (HFpEF), were less likely to receive recommended medical regimen, ACEi or ARB or beta-blockers, compared with patients with reduced ejection fraction (HFrEF) and DM [7,28]. They had also worse blood pressure control, compared with patients with HFrEF and DM, who received the above medical regimens.

Adherence, self-care management and Condition Related Factors

Patients with DM and severe HF were found to have lower self-care management scores, giving priority in managing their HF and showing DM self-management to have less priority and effectiveness [24, 31]. Patients with severe HF (classes II-IV) and DM were found to need more support for self-care management activities and care priorities of their conditions [24]. In contrast, HF patients of classes I and II did not show differences on prioritization and self-care management of the two chronic diseases on physical activity and diet. HF as a comorbidity and severe and not mild HF, were found to increase the difficulty for self-care management in patients with DM [24]. Patients with DM2 and HF are 2.3 times more likely not to follow the medication adherence [31]. Patients with HF and DM were found to consume more saturated fat, protein, dietary fibers, lower carbohydrate and higher levels of sodium than HF patients without DM [12].

Adherence, self-care management and Patient Related Factors

HF and DM self-care intervention had effects on improving HRQoL [30]. Patients with HF and DM in the intervention group improved HF total ($p=.002$) and physical ($p‹.001$) HRQoL scores at three months with improvement at six months and improve HRQoL scores compared with control group at three months($p=.04$). There was also improvement of the health status ratings ($p=.04$) at six months compared to baseline. The intervention group also improved the 6 Minute Walking Test (MWT) distance ($p=.03$) while control declined ($p=.01$).The intervention group increased self-reported physical activity between the baseline and the 6 months ($p=.01$) [30].

The introduction of the empowerment models in the management of patients with HF and DM made patients to have more involvement in their self-care management, which increased their motivation to manage several of their problems raised [27]. Self-monitoring behavior was found to be increased during the study period with an additional 20%-27% of patients in each condition taking a more active role on the management of their condition. In addition, patients were taking more action to adopt healthier eating habits, increase their physical activity and quit smoking $p = .01$) [27].

DISCUSSION

This review is the first systematic review that examined the various factors that influence adherence to the therapy of patients with HF and DM. The factors influencing adherence to the therapy found in eight studies [7, 12, 24, 27, 28, 29, 30, 31] may be divided to three categories: a. Health Care System and Therapy Related Factors, b. Condition Related Factors and c. Patient Related Factors.

a. Health Care System Related Factors and Therapy Related Factors

Health Care system related factors refer to the proper functioning of the health care system and is one of the factors influencing adherence to the therapy of patients with HF and comorbid DM. Empowerment models by the HPs in the Health Care System, can assist patients to arrange their visits with the medical doctors and can give them the necessary support based on their level of care. A good patient-HPs relationship seems to improve adherence to the therapy and clinical parameters of patients with HF and DM who show better control of their conditions [27,32] so they can develop a ‘partnership’ between them with which the patients gradually manage to feel motivated and self-confident. A good relationship among patient-HPs can help the patients to improve their intensity of physical training, take more action, quit smoking and adopt healthier eating habits. These factors may develop the necessary feelings for behavior changes to better control their health status and their clinical indicators, such as low-density lipoprotein levels (LDL), body mass index (BMI) rating and blood pressure values [27, 33]. Such management programs may motivate patients to make behavior changes that can affect their health status. Through motivation, HPs guide patients to find their confidence, take action, and not just give ready-made answers [34, 35]. Motivational interviewing emphasizes the humanistic perspective and person-centered approach when people are normally motivated for further and self-acting development [36, 37]. Person-centered care is the way to demonstrate how symptoms could be integrated into clinical practice [37, 38, 39].

The health care system and HPs must understand better the various needs of patients with HF and DM adapt health care strategies and provide services to balance both; the benefits and the risks of the medical recommendations, as well as patients' preferences [24,40,41]. The HPs must have specific knowledge and training on managing chronic comorbid diseases, such as HF with DM. Patients with HF and comorbid DM generally receive only little help by HPs in setting priorities about self-care management of their comorbid condition [42]. The introduction of telemedicine or telemonitoring in the community, may give nurses a new decision-making tool in the immediate follow up of the chronic patients [43, 44].

Supportive programs by HPs that promote problem solving and develop coping skills, may develop effective behaviors in patients with HF and DM [45] and increase their self-efficacy and access to social support [24, 41,46]. Effective management of HF and DM was the most important factor during the COVID-19 pandemic since DM was found to be correlated with high mortality, showing how patients with DM are more vulnerable to infections or other diseases in general [17,18].

Therapy related factors is another important factor that influences the adherence to therapy in patients with HF and DM. The use of evidence-based therapies for patients with HF and DM must be used for better management of the disease [7] and to reduce the risk of mortality for HFrEF and HFpEF. Also, guideline-recommended therapies are fundamental to be followed for HF and DM patients for better control and not only for patients with HFrEF [28]. HF is a factor that is associated with non-adherence to the pharmacotherapy in DM2 patients and this can be improved through the screening for HF and the interventions [31, 47]. The medication adherence measures can be used as important tool or quality indicator that can improve the performance of health care providers and contribute to health care services improvement and effectiveness [48, 49].

b. Condition Related Factors

Condition-related factors are strong determinants of adherence and include the clinical conditions (physical, psychological, social and vocational), the type and the severity of the disease and the availability of effective therapies [24]. In addition, the impact of the condition related factors depends on how these factors influence patients' risk perception, the importance of adherence treatment, and the priority placed on adherence [50].

There is the necessity for HPs to inform patients with HF and DM, of the importance of setting priorities to their DM self-management and keep their glycosylated hemoglobin (HbA1c) in normal levels, to avoid the hospitalizations [12,13]. Hyperglycemia can produce many and serious macrovascular complications such as CAD, peripheral arterial disease and stroke and /or microvascular complications such as diabetic neuropathy, diabetic nephropathy, and retinopathy [13].These complications lead to the reduction of the HRQoL and to long-term hospitalizations for patients with DM [4, 12,13].

c. **Patient Related Factors**

Patient related factors such as patients' knowledge and beliefs about their illness, motivation and confidence (self-efficacy) for self-care management and expectations on the outcomes of the therapy and the consequences of poor adherence, interact in ways not yet fully understood to influence adherence behavior [14,16,50].

Patients with HF and DM decrease their prioritization for DM management due to the lack of knowledge and information about their illness and its complications. They also ignore how the poor adherence affect their outcomes including mortality and complications [5, 6, 24]. It is common for patients to underestimate the management of DM because DM usually does not cause acute events like those that HF does, such as dyspnea [24]; so they pay more attention to the management of HF. This makes sense since being short of breath is felt, whereas a high sugar is not associated with severe symptoms. Therefore**,** a well-prepared HP team is crucial to achieve the best care and adherence to therapy for patients with HF and DM as indicated by the guidelines and clinical trials [19]. Motivational multidisciplinary programs should be promoted, in order to achieve the proper adherence for these patients [10, 12]. A motivational interview program using the stages of change may increase patients' confidence and improve self-care management [22, 51]; patients may be motivated for lifestyle modification e.g. healthy diet and exercise [27].

The introduction of empowerment models in the management of patients with HF and DM seem to allow the patients the ' partnership' model with the HPs and this will help them to build their self-confidence and the motivation to make lifestyle modification, increase self-monitoring and become more adherence to treatment recommendations [14, 27, 36]. HF and DM management programs including patient empowerment and support, show better outcomes of adherence and help to promote confidence and enhance safety of chronic patient management at home.

Self-care management is a cognitive and behavioral process which refers to regular maintenance tasks like being adherent to medications, engaged in physical activity, following proper diet, monitoring weight gain and management of the symptoms [52, 53]. The educational interventions, which involve patients' collaboration, seem to be more effective that the didactic ones in improving glycemic control, lipids and the weight of the patients. Evidence shows that the involvement of the patients according to their individual needs, supports the effectiveness of self-care management, in chronic diseases [21, 22, 54]. Therefore, a comorbidity approach to self-care education like focusing on behavior approach and developing strategies for maintaining the knowledge about the two diseases seems to be vital for HF-DM patients and more effective in achieving the proper adherence to therapy [30,55].

Limitations

Limitations of this review are confounded regarding the sample size of the participants in the studies. By the observational nature of the studies, unobserved variables may have been present [29].

When studies are not designed as randomized trials, the unmeasured confounders may influence the clinical outcomes in comorbid conditions like in patients with HF and DM [7]. This review could not move forward for meta-analysis due to the heterogeneity of the studies.

CONCLUSIONS

Still, the main reason of deterioration is no adherence to the therapy and many patients feel they are not supported enough to do so. Patients with HF and DM are confronting serious challenges in self-care management of their comorbid condition.

FUTURE DIRECTIONS

It is important that HPs do understand and recognize those challenges in self-care management of comorbid conditions and find strategies and ways to introduce empowerment in the care of the particular population and activate them to participate more in their health care management especially when ageing of population increases the prevalence of comorbidities. In addition, the era of the pandemic of COVID - 19 emerged more than ever and researchers may contribute with interventional studies following similar methodology and evaluating same outcomes. A well-designed care may give the oportunity to the persons with HF and DM to enjoy the best possible quality of care.

Author contributions

All authors have equally contributed and agreed to the manuscript submitted. More specifically:

1. Study design: Katerina Philippou, Ekaterini Lambrinou
2. Data collection: Katerina Philippou, Martha Kyriakou, Ekaterini Lambrinou
3. Data analysis: Katerina Philippou, Martha Kyriakou, Ekaterini Lambrinou
4. Study supervision: Ekaterini Lambrinou
5. Manuscript writing: Katerina Philippou, Ekaterini Lambrinou
6. Critical revisions for important intellectual content: Andreas Charalambous, Vasilios Raftopoulos, Nicos Middleton, Ekaterini Lambrinou

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FIGURES

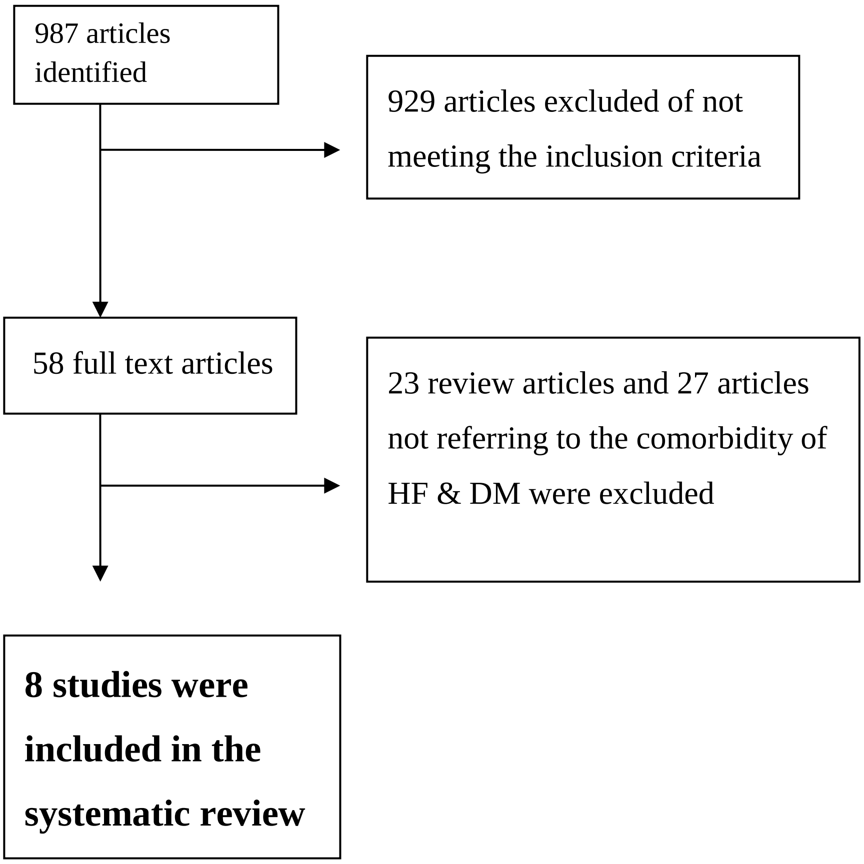

Figure 1. Study selection flowchart

TABLES

Table 1. Overview of the studies

Authors/ Publication date/ Country	Population	Aim	Study design/Methods	Results
1. Greenberg et al, 2007, USA	N=48,612 (Pts with HF and DM) **Pts* with Diabetes** n=20,162 $\bar{x}$** $_{age}$ = 71,5 yrs*** Women (%) =51,6 $\bar{x}$ LVEF (%) = 39,7 **Pts without diabetes** n=28,450 $\bar{x}$ $_{age}$ = 74,4 yrs Women (%) = 51,6 $\bar{x}$ $_{LVEF}$ (%) = 38,5	To provide optimal medical care & education to pts hospitalised for HF The OPTIMIZE-HF (An organized program to initiate lifesaving treatment in hospitalized pts with HF)	Cohort study	-No differences in in-hospital mortality were observed, but HF pts with DM experienced longer length of stay (5.9 vs 5.5 days for Nondiabetic, P < .0001). -In the follow-up cohort DM pts had similar post discharge mortality but increased all-cause rehospitalisation (31.5%. vs 28,2% for non-diabetic pts, P=.006)

Authors/ Publication date/ Country	Population	Aim	Study design / Methods	Results
2. Kerr et al, 2007, USA	N=1,901 (Pts with DM and comorbidities) **Pts with HF and DM** n = 256	To understand how the number, type and severity of comorbidities influence the self-management and treatment priorities of pts with DM The framework for understanding the interplay of DM and comorbidities to access the role of the number, type and severity of comorbid conditions in diabetes prioritization and self-management.	Cross-sectional Observational / Data were used from the HRS (The Health and Retirement Study) Interviews with HRS respondents every 2 yrs. Either by telephone or in person.	Severe but not mild HF was associated with lower DM prioritization and self - management scores. -Mild HF (DM prioritization p=.24 Self-management ability p=.27) -Severe HF (DM prioritization p=.001 Self-management ability p=.003)

Authors/ Publication date/ Country	**Population**	**Aim**	**Study design /Methods**	**Results**
3. Ciccone et al, **2010,** **Italy**	N=573 (Pts with HF and DM)	To evaluate the impact of a disease and care management model and the introduction of 'care manager' nurses, trained in this specialized role, into the primary health care system	Interventional study with convenience sample/ -Project Leonardo used as an 18-month, (baseline, 6 months, 12 months and final measures). -Care managers were provided with a home visit kit with paper copies of the study assessments, patient education	- Patient self-monitoring behavior increased during the study period with an additional 20%-27% of patient in each condition taking a more active role on the management of their condition. -There was statistically significant increase in the number of days per week employed for physical training, from 2.54 to 4.18 days (p<0.0001) and increase time spent doing physical activity, from 19.87 to 32.90 minutes (p<0.0001) per session. -There was statistically significant increase in both diastolic and systolic

			booklets and handouts, screen shots of the data fields and feedback reports from the Informal Care software to use in the pt's home.	BP values (p<0.0001) from initial to final measurements.

Authors/ Publication date/ Country	**Population**	**Aim**	**Study design / Methods**	**Results**
4. Edelmann et al, 2011, Germany	N=994 (Pts with HF and DM) 622 pts were treated with diet or oral antihyperglycaemic drugs 372 pts were treated with insulin inj	To compare HF therapy in pts with DM and HFrEF or HFpEF	Cross-sectional observational / -U/S was performed according to the guidelines of the American Society of Echocardiography.	-The majority of pts with HF and DM and HFrEF were treated with ACE inhibitor or angiotensin receptor blocker or beta-blockers. -Pts with HF and DM and HFpEF were less likely to receive an ACE inhibitor or angiotensin receptor

	EF< 50% n= 824 $\bar{x}_{age}$ = 67,2 yrs Female = 28,9 % **EF ≥ 50%** n=170 $\bar{x}_{age}$ = 69,4 yrs Female = 51,2%			or beta-blockers and had a worse BP control ($p < 0.001$). -In comparison to patients without DM the probability to receive these therapies was increased in patients with DM and HFpEF patients ($p < 0.001$) but not on pts with DM and HFrEF.

Authors/ Publication date/ Country	Population	Aim	Study design / Methods	Results
5. Cha et al, 2012, USA	N= 116 (Pts with HF and DM)	To explore the needs for self-monitoring and self-care education in pts with HF and DM (HF-DM pts) by describing cognitive and affective factors to provide	Cross-sectional correlation / A baseline patient data and 12-week Patient and family dyad intervention to improve dietary and medication taking self-management	- Pts with HF and DM had higher rates of sleep apnea, (45.7%, p=.003) and depression (43.5%, p=.046) than those with only HF - Pts with HF and DM were found that they consumed more saturated fat (182.89±99.58),

		guidance on developing effective self-management education	behaviors in pts with HF, Demographic and co-morbidity were assessed regarding age, gender, ethnicity, marital status etc. The Charlson Comorbidity Index was used to assess co-morbid conditions. Physical function was assessed with the assessed with 6MWT Health care resource use was assessed with a Health Resources Utilization Questionnaire Previous HF education measured with 8 yes/no questions.	protein (77.00±25.52), dietary fibers (16.38±8.90), and lower carbohydrate (187.33±81.66) than pts with HF without DM - Pts with HF and DM consumed higher levels of sodium, greater than 250 mg each day, more than those patients without DM

			Depressive symptoms were measured with the Beck Depression Inventory II Social support like the relationship with health care provider (Health Care Climate Questionnaire),. HF knowledge was assessed with a 27-item scale using multiple choice questions Medication taking self-efficacy and low sodium diet self-efficacy were measured by two self-efficacy scales derived from the perceived competence	

			scales developed by Williams and al Medication taking behavior was measured by subjective and objective scales Dietary intake was assessed with a three-day food record maintained by the participant who recorded all meals and snacks including beverages over three days, preparation techniques and details of condiments		

Authors/ Publication date/ Country	Population	Aim	Study design / Methods	Results
6. Kapoor et al, 2011, USA	N = 54,352 (HF pts hospitalized with a history of DM) Age (y),mean ± SD= 71±13 (with DM) Women= 50% (with DM) HF-55.1 % (History of HF with DM) EF< 40% = 46.6 %	To clarify the influence of DM on health care quality and in-hospital outcomes in a contemporary cohort of pts hospitalized with HF	Prospective observational study/ -The follow up time was between January 2005 and January 2010 comparing pts with HF, with and without DM ,methodology not applicable	--Patients with DM were less likely to receive smoking cessation counseling (OR 0.89, 95% CI 0.81-0.98) (p =.022) and blood pressure control (OR 0.81, 95% CI 0.78-0.84) (p < .001). -Patients with DM were more likely to receive an aldosteron antagonist for reduced left ventricular ejection fraction (OR 1.05, 95% CI 1.00-1.11) (p= .035) , lipid-lowering agent (OR 1.33, 95% CI 1.26-1.41) (p < .001), and influenza vaccination (OR 1.05, 95% CI 1.01-1.09)(p= .024). -DM was independently associated with longer hospital stay (p< .001) but not within-hospital mortality (p= .111).

Authors/ Publication date/ Country	Population	Aim	Study Design / Methods	Results
7.Dunbar et al 2015, **USA**	N= 134 (patients with HF and DM)	To test an integrated self-care intervention for pts with HF and DM	RCT / -The control group received standard HF and DM educational brochures with follow up phone contact -The intervention group received education/ counselling on HF-DM self-care (diet, medications, self-monitoring, symptoms and physical activity) with follow up home visits	-patients with HF and DM in the intervention group improved HF total(p=.002) and physical (p‹.001) QOL scores at 3 months with improvement at 6 months and improve QOL scores compared with control group at 3 months(p=.04). -There was also improvement of the health status ratings (p=.04) at 6 months compared to baseline. -The intervention group also improved the 6MWT distance (p=.03) while control declined (p=.01). -The intervention group increased self-reported physical activity between the baseline and the 6 months (p= .01).

			and phone counselling. - Questionaires for HF and DM specific and overall QoL, Physical activity frequency and Physical function (6MWT), at baseline, 3 and 6 months.	

Authors/ Publication date/ Country	**Population**	**Aim**	**Study Design / Methods**	**Results**
8. Peres et al 2019 **Brazil**	N= 200	The exploration of cardiovascular consequences associated with compliance and no-adherence among DM 2 in Brazilian pts	- Cross –sectional study / -The tests were used: Morisky-Green modified (MGT), Diabetes Complication(DC), Complexity of Pharmacotherapy(CP), MedTake(MT) and	-The 35% of the patients who did not follow the recommendations of the treatment were those with the comorbidity of HF and DM.

			Auto-Comliance Test(ACT).	

Table 2. Quality assessment components and ratings for EPHPP instrument (Thomas et al (2004)

COMPONENTS	STRONG	MODERATE	WEAK
Selection bias	Very likely to be representative of the target population and greater than 80% participation rate	Somewhat likely to be representative of the target population and 60–79% participation rate	All other responses or not stated
Design	RCT and CCT	Cohort analytic, case-control, cohort, or an interrupted time series	All other designs or design not state
Confounders	Controlled for at least 80% of confounders	Controlled for 60–79% of confounders	Confounders not controlled for, or not stated

Blinding	Blinding of outcome assessor and study participants to intervention status and/or research question	Blinding of either outcome assessor or study participants	Outcome assessor and study participants are aware of intervention status and/or research question
Data collection methods	Tools are valid and reliable	Tools are valid but reliability not described	No evidence of validity or reliability
Withdrawals and dropouts	Follow-up rate of > 80% of participants	Follow-up rate of 60–79% of participants	Follow-up rate of < 60% of participants or withdrawals and dropouts not described

APPENDIX III

‘Guide’ assistant for focus groups

Ερωτηματολόγιο για Focus Groups
1) Continuing Person -Centred care (CPCC)
2) Social Support
3) Supportive care
4) Palliative care
5) Self- Management

CPCC

1) Συμμετέχετε στις αποφάσεις για την θεραπευτική προσέγγιση; (φάρμακα, αλλαγή τρόπου ζωής, άσκηση)

2) Θα θέλατε να συμμετέχετε στη λήψη αποφάσεων;

3) Πως θα θέλατε να είναι η θεραπευτική προσέγγιση με τους Επαγγελματίες υγείας; (γιατρούς, νοσηλευτές κλπ)

4) Έχετε άλλες ανάγκες που χρειάζεστε να καλυφθούν ή βοήθεια; Αν ναι ποιες;

Social Support

1) Ποιες υπηρεσίες θα ήταν βοηθητικές για εσας; (κρατικές, δημοτικές, κοινωνικές);

2) Τι είδους υποστήριξης θα θέλατε να έχετε; (οικονομική/καλύτερο δίκτυο υπηρεσιών);

Supportive care

1) Τι είδους φροντίδα χρειάζεστε; Τι θα θέλατε να περιλαμβάνει η φροντίδα από τους επαγγελματίες υγείας (νοσηλευτές, γιατρούς , φυσιοθεραπευτές)

2) Πιστεύετε θα σας βοηθούσε κάποιου είδους εκπαίδευσης, πληροφόρησης για την ασθένεια σας;

3) Τι είδους επικοινωνία θα επιθυμούσατε να έχετε με τους Επαγγελματίες Υγείας (συχνότητα/περιεχόμενο)

4) Θα θέλατε να έχετε συμμετοχή στις αποφάσεις για τις επιλογές ή τις εναλλακτικές που υπάρχουν στη θεραπεία σας;

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5) Ποιες είναι οι ψυχολογικές σας ανάγκες; Τι θα σας βοηθούσε (συναντήσεις σαν αυτές και σε ποια συχνότητα)

6) Είστε ικανοποιημένοι από την ενημέρωση και υποστήριξη που έχετε από τις υπηρεσίες υγείας;

7) Τι νομίζετε ότι θα σας βοηθούσε για να διατηρείται η καρδιά και η υγεία σας σε καλή κατάσταση;

8) Τι νομίζετε ότι θα σας βοηθούσε για να έχετε καλή ποιότητα ζωής;

9) Τι γίνεται μετά την έξοδο από το νοσοκομείο;

10) Υπάρχει κάποιο πρόγραμμα υποστήριξης;

11) Υπάρχει κάποιος επαγγελματίας υγείας στον οποίο μπορείτε να απευθύνεστε εάν χρειάζεστε κάτι;

12) Νιώθετε άνετα να συζητήσετε κάποιο πρόβλημα ή κάτι που σας απασχολεί με τον επαγγελματία υγείας σας; Αν ναι, ποιο; (καρδιολογο, γενικό γιατρό, παθολογο, νοσηλευτή;)

Palliative care

Έχετε άλλες ανάγκες όπως πνευματικές, παρηγορητική φροντίδα που θα θέλατε να καλυφθούν ή να συζητήσετε;

Self -Management

1) Μπορείτε να μας πείτε τι δυσκολίες αντιμετωπίζετε με τις καθημερινές σας δραστηριότητες;

- Υγιεινή/ μεταφορές –περπάτημα

● Χρειάζεστε βοήθεια για τις πιο πάνω δραστηριότητες (π.χ. βοήθεια ατόμου ή βοηθήματος όπως μπαστούνι)
2) Τι κάνετε για να παραμείνετε υγιείς; (μέτρηση βάρους, καταγραφή υγρών κλπ)
● Τι θα σας βοηθούσε για να διατηρήσετε αυτές τις δραστηριότητες καθημερινά;
3) Ασκείστε;
● Τι είδος άσκησης/δραστηριότητες θα ήταν πιο ευχάριστη για εσάς ώστε να την εντάξετε στην καθημερινότητά σας;
● Τι θα σας βοηθούσε να διατηρήσετε αυτή τη συνήθεια;
● Πως Θα θέλατε να ασκείστε

APPENDIX IV

ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ

για συμμετοχή σε πρόγραμμα έρευνας

(Τα έντυπα αποτελούνται συνολικά από ……6………… σελίδες)

Καλείστε να συμμετάσχετε σε ένα ερευνητικό πρόγραμμα. Πιο κάτω (βλ. **«Πληροφορίες για Ασθενείς ή/και Εθελοντές»**) θα σας δοθούν εξηγήσεις σε απλή γλώσσα σχετικά με το τι θα ζητηθεί από εσάς ή/και τι θα σας συμβεί σε εσάς, εάν συμφωνήσετε να συμμετάσχετε στο πρόγραμμα. Θα σας περιγραφούν οποιοιδήποτε κίνδυνοι μπορεί να υπάρξουν ή ταλαιπωρία που τυχόν θα υποστείτε από την συμμετοχή σας στο πρόγραμμα. Θα σας επεξηγηθεί με κάθε λεπτομέρεια τι θα ζητηθεί από εσάς και ποιος ή ποιοι θα έχουν πρόσβαση στις πληροφορίες ή/και άλλο υλικό που εθελοντικά θα δώσετε για το πρόγραμμα. Θα σας δοθεί η χρονική περίοδος για την οποία οι υπεύθυνοι του προγράμματος θα έχουν πρόσβαση στις πληροφορίες ή/και υλικό που θα δώσετε. Θα σας επεξηγηθεί τι ελπίζουμε να μάθουμε από το πρόγραμμα σαν αποτέλεσμα και της δικής σας συμμετοχής. Επίσης, θα σας δοθεί μία εκτίμηση για το όφελος που μπορεί να υπάρξει για τους ερευνητές ή/και χρηματοδότες αυτού του προγράμματος. **Δεν πρέπει να συμμετάσχετε, εάν δεν επιθυμείτε ή εάν έχετε οποιουσδήποτε ενδοιασμούς που αφορούν την συμμετοχή σας στο πρόγραμμα.** Εάν αποφασίσετε να συμμετάσχετε, πρέπει να αναφέρετε εάν είχατε συμμετάσχει σε οποιοδήποτε άλλο πρόγραμμα έρευνας μέσα στους τελευταίους 12 μήνες. Εάν αποφασίσετε να μην συμμετάσχετε και είστε ασθενής, η θεραπεία σας δεν θα επηρεαστεί από την απόφασή σας. **Είστε ελεύθεροι να αποσύρετε οποιαδήποτε στιγμή εσείς επιθυμείτε την συγκατάθεση για την συμμετοχή σας στο πρόγραμμα.** Εάν είστε ασθενής, η απόφασή σας να αποσύρετε την συγκατάθεση σας, δεν θα έχει οποιεσδήποτε επιπτώσεις στην θεραπεία σας. Έχετε το δικαίωμα να υποβάλετε τυχόν παράπονα ή καταγγελίες, που αφορούν το πρόγραμμα στο οποίο συμμετέχετε, προς την Επιτροπή Βιοηθικής που ενέκρινε το πρόγραμμα ή ακόμη και στην Εθνική Επιτροπή Βιοηθικής Κύπρου.

Πρέπει όλες οι σελίδες των εντύπων συγκατάθεσης να φέρουν το ονοματεπώνυμο και την υπογραφή σας.

Σύντομος Τίτλος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε
«Η υποστηρικτική φροντίδα στη διαχείριση ασθενών με καρδιακή ανεπάρκεια»
Υπεύθυνος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε
Δρ Αικατερίνη Λαμπρινού - Αναπληρώτρια καθηγήτρια

Επίθετο:	………………………………………………………	Όνομα:	…………………………………………
Υπογραφή:		Ημερομηνία:	

……………………………………………………..……..……………

ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ για συμμετοχή σε πρόγραμμα έρευνας (Τα έντυπα αποτελούνται συνολικά από …6….. σελίδες)
Σύντομος Τίτλος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε
«Η υποστηρικτική φροντίδα στη διαχείριση ασθενών με καρδιακή ανεπάρκεια»

Δίδετε συγκατάθεση για τον εαυτό σας ή για κάποιο άλλο άτομο;	
Εάν πιο πάνω απαντήσατε για κάποιον άλλο, τότε δώσετε λεπτομέρειες και το όνομα του.	

Ερώτηση	ΝΑΙ ή ΟΧΙ

Συμπληρώσατε τα έντυπα συγκατάθεσης εσείς προσωπικά;	
Τους τελευταίους 12 μήνες έχετε συμμετάσχει σε οποιοδήποτε άλλο ερευνητικό πρόγραμμα;	
Διαβάσατε και καταλάβατε τις πληροφορίες για ασθενείς ή/και εθελοντές;	
Είχατε την ευκαιρία να ρωτήσετε ερωτήσεις και να συζητήσετε το Πρόγραμμα;	
Δόθηκαν ικανοποιητικές απαντήσεις και εξηγήσεις στα τυχόν ερωτήματά σας;	
Καταλαβαίνετε ότι μπορείτε να αποσυρθείτε από το πρόγραμμα, όποτε θέλετε;	
Καταλαβαίνετε ότι, εάν αποσυρθείτε, δεν είναι αναγκαίο να δώσετε οποιεσδήποτε εξηγήσεις για την απόφαση που πήρατε;	
(Για ασθενείς) καταλαβαίνετε ότι, εάν αποσυρθείτε, δεν θα υπάρξουν επιπτώσεις στην τυχόν θεραπεία που παίρνετε ή που μπορεί να πάρετε μελλοντικά;	
Συμφωνείτε να συμμετάσχετε στο πρόγραμμα;	
Με ποιόν υπεύθυνο μιλήσατε;	

Επίθετο:	………………………………………………………	Όνομα:	…………………………………………
Υπογραφή:		Ημερομηνία:	

ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ

για συμμετοχή σε πρόγραμμα έρευνας

(Τα έντυπα αποτελούνται συνολικά από ………6…….. σελίδες)

Σύντομος Τίτλος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε

«Η υποστηρικτική φροντίδα στη διαχείριση ασθενών με καρδιακή ανεπάρκεια »

ΠΛΗΡΟΦΟΡΙΕΣ ΓΙΑ ΑΣΘΕΝΕΙΣ ή/και ΕΘΕΛΟΝΤΕΣ

Η παρούσα μελέτη διεξάγεται από το Τμήμα Νοσηλευτικής του Τεχνολογικού Πανεπιστημίου Κύπρου, για να διερευνηθεί ο ρόλος της υποστηρικτικής φροντίδας στη διαχείριση ασθενών με καρδιακή ανεπάρκεια και ενδεχόμενη συννοσυρότητα σακχαρώδη διαβήτη, στην Κύπρο. Η έρευνα θα διεξαχθεί στο πλαίσιο εκπόνησης Διδακτορικής Διατριβής με επιστημονική υπεύθυνη τη Δρ. Αικατερίνη Λαμπρινού, Αναπληρώτρια καθηγήτρια στο Τμήμα Νοσηλευτικής του Τεχνολογικού Πανεπιστημίου Κύπρου. Κύριοι ερευνητές είναι η Δρ. Αικατερίνη Λαμπρινού και η κα Κατερίνα Φιλίππου, υποψήφια διδάκτωρ στη διαχείριση ασθενών με καρδιακή ανεπάρκεια και ενδεχόμενη συννοσυρότητα σακχαρώδη διαβήτη.

Σκοπός και στόχοι της έρευνα :

Ο σκοπός της προτεινόμενης μελέτης είναι η ανάπτυξη ενός νοσηλευτικού προγράμματος το οποίο να περιλαμβάνει υποστηρικτική φροντίδα με σκοπό τη βελτίωση της τήρησης της θεραπείας των ασθενών, καθώς και της αυτοφροντίδας τους, σε σχέση με τη «συνήθη» θεραπεία που ακολουθείται στην Κύπρο όσον αφορά στην τήρηση της θεραπείας και της ποιότητας ζωής των ασθενών με καρδιακή ανεπάρκεια και ενδεχόμενη συννοσυρότητα σακχαρώδη διαβήτη.

Η ερευνητική υπόθεση και τα αναμενόμενα αποτελέσματα της προτεινόμενης μελέτης είναι:

Ερευνητική υπόθεση

Η ερευνητική υπόθεση της προτεινόμενης μελέτης είναι ότι η υποστηρικτική φροντίδα είναι ευεργετική για τους ασθενείς με καρδιακή ανεπάρκεια και ενδεχόμενη συννοσυρότητα σακχαρώδη διαβήτη. συγκριτικά με την «συνήθη» θεραπεία που ακολουθείται στην Κύπρο όσον αφορά στην αυτοφροντίδα αυτής της ομάδας ασθενών, την τήρηση της θεραπείας και τη βελτίωση της ποιότητας ζωής τους.

Επίθετο:	…………………………………………………………	Όνομα:	…………………………………………
Υπογραφή:		Ημερομηνία:	

ΠΛΗΡΟΦΟΡΙΕΣ ΓΙΑ ΑΣΘΕΝΕΙΣ ή/και ΕΘΕΛΟΝΤΕΣ, συνέχεια:

Αναμενόμενα αποτελέσματα

Η κυριότερη έκβαση είναι η βελτίωση της σχετιζόμενης με την υγεία ποιότητας ζωής των ασθενών με καρδιακή ανεπάρκεια διαμέσου της υποστηρικτικής φροντίδας.

Οι δευτερεύουσες εκβάσεις είναι η ελάττωση των οξέων συμβάντων (π.χ. θνησιμότητας, νοσηρότητας και εισαγωγών στα νοσηλευτήρια), η βελτίωση της αυτοφροντίδας της αυτοπεποίθησης και των γνώσεων των ασθενών με καρδιακή ανεπάρκεια.

Σε κανένα σημείο της έρευνας δεν απαιτείται και δεν καταγράφεται το ονοματεπώνυμο σας ή οποιοδήποτε άλλο στοιχείο το οποίο θα μπορούσε να προσδιορίσει την ταυτότητά σας. Επιπλέον, σε κανένα στάδιο της μελέτης δεν πρόκειται να γίνει αναφορά στα νοσοκομεία ή στις υπηρεσίες στις οποίες πραγματοποιήθηκε η μελέτη, ή στα στοιχεία σας. Η ανωνυμία, η εμπιστευτικότητα και το απόρρητο των πληροφοριών θα προστατευθούν, τόσο κατά τη διάρκεια, όσο και μετά το τέλος της ερευνητικής αυτής εργασίας.

Σχετικά με το πιο πάνω ερευνητικό πρόγραμμα, εφόσον πληρούνται τα κριτήρια εισδοχής θα ενταχθείτε, είτε στην ομάδα ελέγχου, είτε στην ομάδα παρέμβασης. Εάν ενταχθείτε στην ομάδα έλεγχου, τότε απλά θα λαμβάνετε τη «συνήθη» θεραπεία που ακολουθείται στα νοσηλευτήρια της Κύπρου πριν από την έξοδο σας από το νοσοκομείο, η οποία περιλαμβάνει γενικές οδηγίες-πληροφορίες για τη διαχείριση της καρδιακής ανεπάρκειας (και του σακχαρώδη διαβήτη) από τους επαγγελματίες υγείας. Εάν ενταχθείτε στην ομάδα παρέμβασης θα κληθείτε να συμμετάσχετε σε ένα πρόγραμμα που περιλαμβάνει την παροχή υποστηρικτικής φροντίδας, σύμφωνα με τα θέματα που αναδείχθηκαν μέσω ομάδων εστιασμένης συζήτησης για άτομα με καρδιακή ανεπάρκεια. Εάν λάβετε μέρος στις ομάδες εστιασμένης συζήτησης, η συζήτηση θα μαγνητοφωνηθεί ως μέρος του τρόπου συλλογής των δεδομένων και διευκόλυνσης στην καλύτερη διαχείριση των δεδομένων. Πρόσβαση στο ηχογραφημένο υλικό θα έχουν μόνο οι κύριοι ερευνητές.

Επίθετο:	…………………………………………………………	Όνομα:	………………………………………
Υπογραφή:		Ημερομηνία:	

ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ

για συμμετοχή σε πρόγραμμα έρευνας

(Τα έντυπα αποτελούνται συνολικά από ……6……… σελίδες)

Σύντομος Τίτλος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε

«Η υποστηρικτική φροντίδα στη διαχείριση ασθενών με καρδιακή ανεπάρκεια»

Μέσω της συνεχούς επικοινωνίας που θα έχετε με τα άτομα του προγράμματος π.χ συνεχής επικοινωνία είτε μέσω τηλεφώνου, είτε/και μέσω μηνυμάτων SMS, είτε/και διαμέσου μέσων κοινωνικής δικτύωσης με τους επαγγελματίες υγείας που θα απαρτίζουν την ομάδα στήριξης, θα αναδειχθούν οι ατομικές σας ανάγκες σε θέματα που αφορούν στις γνώσεις, απορίες, την αυτοφροντίδα σας στο θέμα της καρδιακής ανεπάρκειας και του σακχαρώδη διαβήτη, θα αυξηθεί η αυτοπεποίθηση σας, θα ενθαρρυνθείτε να ακολουθείτε υγιείς συμπεριφορές και να γίνετε ανεξάρτητοι όσον αφορά στη διαχείριση των διαφόρων καταστάσεων που ίσως προκύψουν κατά τη διάρκεια της ζωής σας, ακολουθώντας ένα εξατομικευμένο πρόγραμμα σύμφωνα με τις δικές σας ανάγκες για το πώς θα διαχειριστείτε την κατάσταση σας. Για παράδειγμα, είναι δυνατό να χρειαστείτε εκπαίδευση και καθοδήγηση όσον αφορά στις διατροφικές σας συνήθειες, την άσκηση σας, την τήρηση της φαρμακευτικής ή μη φαρμακευτικής σας θεραπείας, την επικοινωνία σας με τους επαγγελματίες υγείας σε διάφορα θέματα που σας αφορούν, όπως απορίες για διατροφικά σκευάσματα κλπ. Όλα αυτά θα έχουν σκοπό τη βελτίωση της αυτοφροντίδας σας στη διαχείριση της καρδιακής ανεπάρκειας και του σακχαρώδη διαβήτη, μαθαίνοντας μέσα από την γνώση και την κοινωνική στήριξη από τους επαγγελματίες υγείας πώς και πότε μπορείτε να κάνετε αλλαγές στον τρόπο ζωής σας για βελτίωση της ποιότητας της ζωής σας, βασισμένοι στις δικές σας δυνάμεις, με σκοπό τη βελτίωση της αυτοπεποίθησης και της αυτοαποτελεσματικότητας.

Όλες οι μετρήσεις (ομάδας ελέγχου και ομάδας παρέμβασης) θα κωδικοποιηθούν για την προστασία των προσωπικών σας δεδομένων. Οι μετρήσεις θα διατηρηθούν μόνο κατά τη διάρκεια της έρευνας, ενώ με την ολοκλήρωσή της, θα καταστραφούν.

Θα χρειαστεί να συμπληρώσετε, τόσο η ομάδα ελέγχου, όσο και η ομάδα παρέμβασης, κάποια ερωτηματολόγια σχετικά με τα πιθανά αποτελέσματα αυτού του προγράμματος. Πρόκειται για απλά ερωτηματολόγια, τα οποία μπορούν να συμπληρωθούν σε σύντομο χρονικό διάστημα. Τα ερωτηματολόγια θα είναι ανώνυμα και κωδικοποιημένα και οι συμμετέχοντες δε θα μπορούν να αναγνωρισθούν σε κανένα στάδιο της έρευνας.

Επίθετο:	…………………………………………………………	Όνομα:	………………………………………
Υπογραφή:		Ημερομηνία:	

ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ

για συμμετοχή σε πρόγραμμα έρευνας

(Τα έντυπα αποτελούνται συνολικά από ……6……… σελίδες)

Σύντομος Τίτλος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε

«Η υποστηρικτική φροντίδα στη διαχείριση ασθενών με καρδιακή ανεπάρκεια »

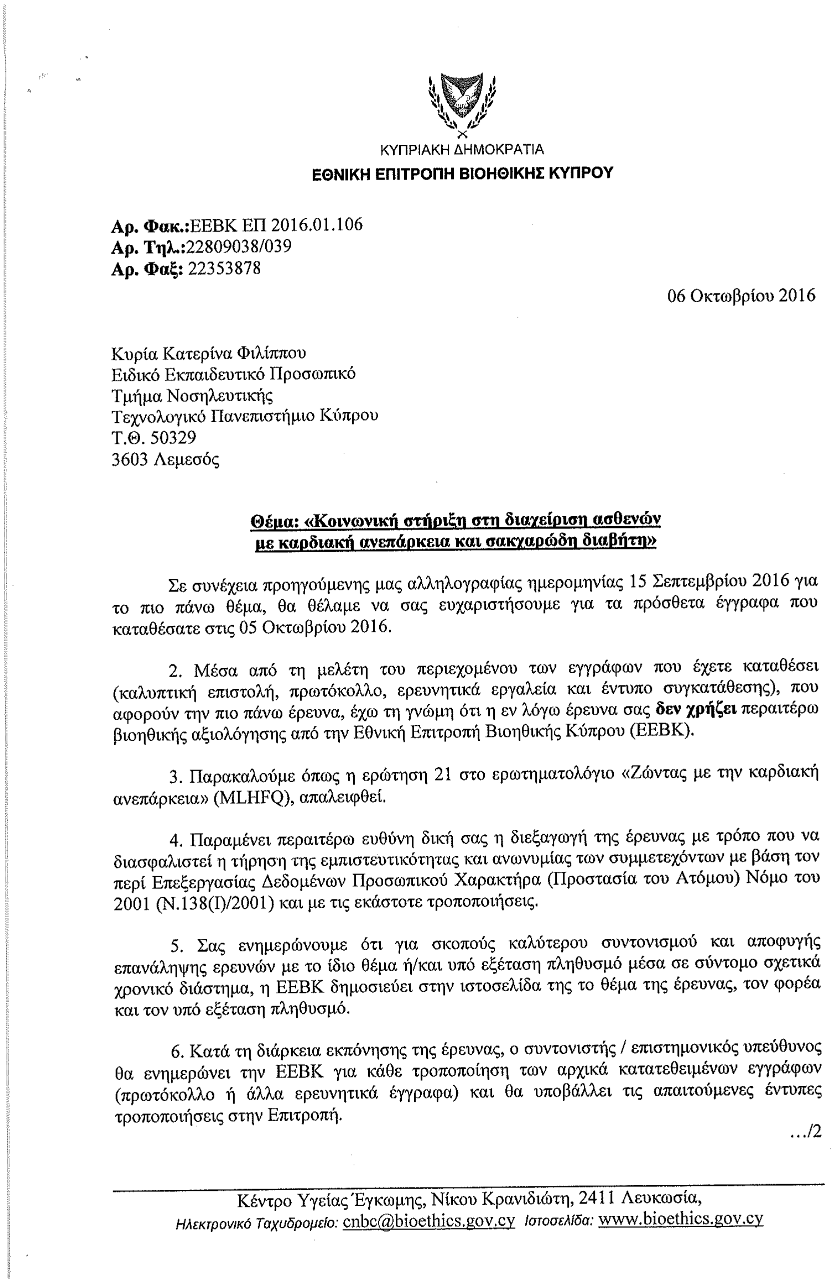
Εάν μετά από τις πληροφορίες που αφορούν στην έρευνα, αποφασίσετε να συμμετάσχετε στο ερευνητικό έργο, τότε διατηρείται το δικαίωμα αποχώρησης σε οποιαδήποτε στιγμή κρίνετε εσείς αναγκαίο, χωρίς να είσαστε αναγκασμένοι να δώσετε οποιεσδήποτε εξηγήσεις αλλά και χωρίς οποιεσδήποτε επιπτώσεις στη φροντίδα που λαμβάνετε. Εάν για οποιοδήποτε λόγο, οι παραπάνω πληροφορίες αδυνατούν να απαντήσουν σε κάποιο ή κάποια από τα ερωτήματα σας, τότε μπορείτε να απευθυνθείτε στην Επιστημονική Υπεύθυνη

Δρ. Αικατερίνη Λαμπρινού
Τμήμα Νοσηλευτικής ΤΕΠΑΚ, Σχολή Επιστημών Υγείας
15 Βραγαδίνου, 3041, Λεμεσός
ΚΥΠΡΟΣ
Τηλ. 25002030
Ηλεκτρονικό Ταχυδρομείο ekaterini.lambrinou@cut.ac.cy

Επίθετο:	…………………………………………………………	Όνομα:	…………………………………………
Υπογραφή:		Ημερομηνία:	

APPENDIX V

Approval by the Cyprus Bioethics Committee and by the Data Protection Office.



ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ
ΕΘΝΙΚΗ ΕΠΙΤΡΟΠΗ ΒΙΟΗΘΙΚΗΣ ΚΥΠΡΟΥ

Αρ. Φακ.:ΕΕΒΚ ΕΠ 2016.01.106
Αρ. Τηλ.:22809038/039
Αρ. Φαξ: 22353878

06 Οκτωβρίου 2016

Κυρία Κατερίνα Φιλίππου
Ειδικό Εκπαιδευτικό Προσωπικό
Τμήμα Νοσηλευτικής
Τεχνολογικό Πανεπιστήμιο Κύπρου
Τ.Θ. 50329
3603 Λεμεσός

Θέμα: «Κοινωνική στήριξη στη διαχείριση ασθενών με καρδιακή ανεπάρκεια και σακχαρώδη διαβήτη»

Σε συνέχεια προηγούμενης μας αλληλογραφίας ημερομηνίας 15 Σεπτεμβρίου 2016 για το πιο πάνω θέμα, θα θέλαμε να σας ευχαριστήσουμε για τα πρόσθετα έγγραφα που καταθέσατε στις 05 Οκτωβρίου 2016.

2. Μέσα από τη μελέτη του περιεχομένου των εγγράφων που έχετε καταθέσει (καλυπτική επιστολή, πρωτόκολλο, ερευνητικά εργαλεία και έντυπο συγκατάθεσης), που αφορούν την πιο πάνω έρευνα, έχω τη γνώμη ότι η εν λόγω έρευνα σας **δεν χρήζει** περαιτέρω βιοηθικής αξιολόγησης από την Εθνική Επιτροπή Βιοηθικής Κύπρου (ΕΕΒΚ).

3. Παρακαλούμε όπως η ερώτηση 21 στο ερωτηματολόγιο «Ζώντας με την καρδιακή ανεπάρκεια» (MLHFQ), απαλειφθεί.

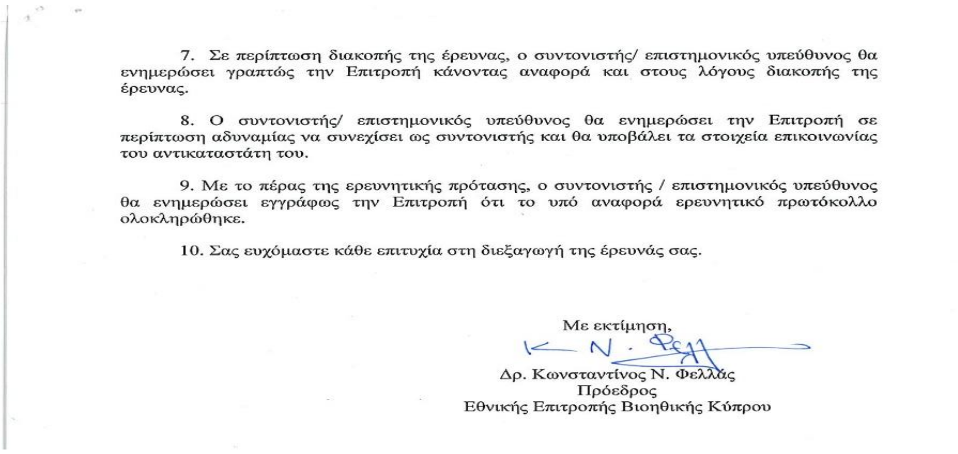
4. Παραμένει περαιτέρω ευθύνη δική σας η διεξαγωγή της έρευνας με τρόπο που να διασφαλιστεί η τήρηση της εμπιστευτικότητας και ανωνυμίας των συμμετεχόντων με βάση τον περί Επεξεργασίας Δεδομένων Προσωπικού Χαρακτήρα (Προστασία του Ατόμου) Νόμο του 2001 (N.138(I)/2001) και με τις εκάστοτε τροποποιήσεις.

5. Σας ενημερώνουμε ότι για σκοπούς καλύτερου συντονισμού και αποφυγής επανάληψης ερευνών με το ίδιο θέμα ή/και υπό εξέταση πληθυσμό μέσα σε σύντομο σχετικά χρονικό διάστημα, η ΕΕΒΚ δημοσιεύει στην ιστοσελίδα της το θέμα της έρευνας, τον φορέα και τον υπό εξέταση πληθυσμό.

6. Κατά τη διάρκεια εκπόνησης της έρευνας, ο συντονιστής / επιστημονικός υπεύθυνος θα ενημερώνει την ΕΕΒΚ για κάθε τροποποίηση των αρχικά κατατεθειμένων εγγράφων (πρωτόκολλο ή άλλα ερευνητικά έγγραφα) και θα υποβάλλει τις απαιτούμενες έντυπες τροποποιήσεις στην Επιτροπή.

…/2

Κέντρο Υγείας Έγκωμης, Νίκου Κρανιδιώτη, 2411 Λευκωσία,
Ηλεκτρονικό Ταχυδρομείο: cnbc@bioethics.gov.cy *Ιστοσελίδα:* www.bioethics.gov.cy



7. Σε περίπτωση διακοπής της έρευνας, ο συντονιστής/ επιστημονικός υπεύθυνος θα ενημερώσει γραπτώς την Επιτροπή κάνοντας αναφορά και στους λόγους διακοπής της έρευνας.

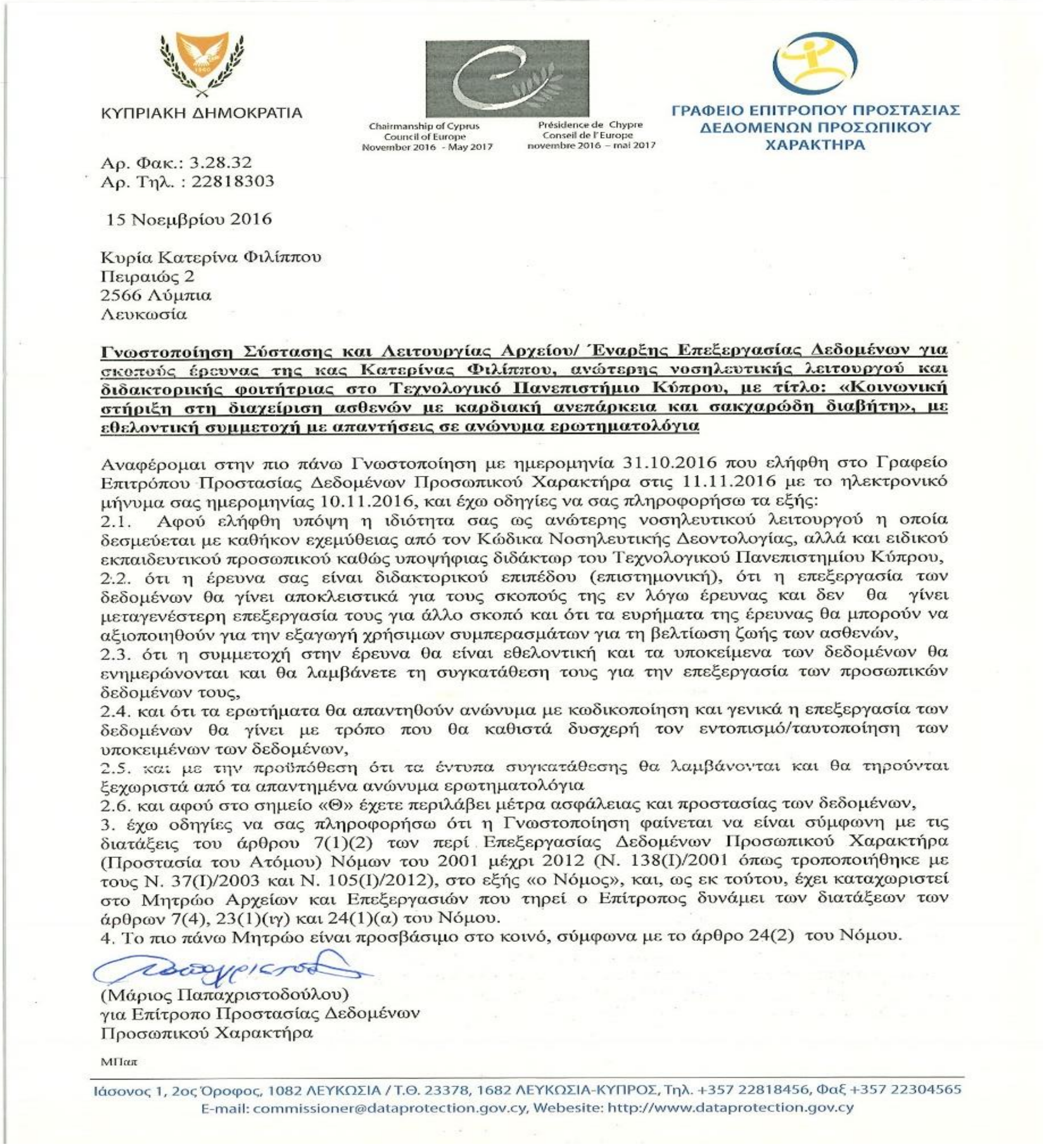
8. Ο συντονιστής/ επιστημονικός υπεύθυνος θα ενημερώσει την Επιτροπή σε περίπτωση αδυναμίας να συνεχίσει ως συντονιστής και θα υποβάλει τα στοιχεία επικοινωνίας του αντικαταστάτη του.

9. Με το πέρας της ερευνητικής πρότασης, ο συντονιστής / επιστημονικός υπεύθυνος θα ενημερώσει εγγράφως την Επιτροπή ότι το υπό αναφορά ερευνητικό πρωτόκολλο ολοκληρώθηκε.

10. Σας ευχόμαστε κάθε επιτυχία στη διεξαγωγή της έρευνάς σας.

Με εκτίμηση,

Δρ. Κωνσταντίνος Ν. Φελλάς
Πρόεδρος
Εθνικής Επιτροπής Βιοηθικής Κύπρου



ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ

Chairmanship of Cyprus
Council of Europe
November 2016 - May 2017

Présidence de Chypre
Conseil de l'Europe
novembre 2016 – mai 2017

ΓΡΑΦΕΙΟ ΕΠΙΤΡΟΠΟΥ ΠΡΟΣΤΑΣΙΑΣ
ΔΕΔΟΜΕΝΩΝ ΠΡΟΣΩΠΙΚΟΥ
ΧΑΡΑΚΤΗΡΑ

Αρ. Φακ.: 3.28.32
Αρ. Τηλ. : 22818303

15 Νοεμβρίου 2016

Κυρία Κατερίνα Φιλίππου
Πειραιώς 2
2566 Λύμπια
Λευκωσία

<u>Γνωστοποίηση Σύστασης και Λειτουργίας Αρχείου/ Έναρξης Επεξεργασίας Δεδομένων για σκοπούς έρευνας της κας Κατερίνας Φιλίππου, ανώτερης νοσηλευτικής λειτουργού και διδακτορικής φοιτήτριας στο Τεχνολογικό Πανεπιστήμιο Κύπρου, με τίτλο: «Κοινωνική στήριξη στη διαχείριση ασθενών με καρδιακή ανεπάρκεια και σακχαρώδη διαβήτη», με εθελοντική συμμετοχή με απαντήσεις σε ανώνυμα ερωτηματολόγια</u>

Αναφέρομαι στην πιο πάνω Γνωστοποίηση με ημερομηνία 31.10.2016 που ελήφθη στο Γραφείο Επιτρόπου Προστασίας Δεδομένων Προσωπικού Χαρακτήρα στις 11.11.2016 με το ηλεκτρονικό μήνυμα σας ημερομηνίας 10.11.2016, και έχω οδηγίες να σας πληροφορήσω τα εξής:
2.1. Αφού ελήφθη υπόψη η ιδιότητα σας ως ανώτερης νοσηλευτικού λειτουργού η οποία δεσμεύεται με καθήκον εχεμύθειας από τον Κώδικα Νοσηλευτικής Δεοντολογίας, αλλά και ειδικού εκπαιδευτικού προσωπικού καθώς υποψήφιας διδάκτωρ του Τεχνολογικού Πανεπιστημίου Κύπρου,
2.2. ότι η έρευνα σας είναι διδακτορικού επιπέδου (επιστημονική), ότι η επεξεργασία των δεδομένων θα γίνει αποκλειστικά για τους σκοπούς της εν λόγω έρευνας και δεν θα γίνει μεταγενέστερη επεξεργασία τους για άλλο σκοπό και ότι τα ευρήματα της έρευνας θα μπορούν να αξιοποιηθούν για την εξαγωγή χρήσιμων συμπερασμάτων για τη βελτίωση ζωής των ασθενών,
2.3. ότι η συμμετοχή στην έρευνα θα είναι εθελοντική και τα υποκείμενα των δεδομένων θα ενημερώνονται και θα λαμβάνετε τη συγκατάθεση τους για την επεξεργασία των προσωπικών δεδομένων τους,
2.4. και ότι τα ερωτήματα θα απαντηθούν ανώνυμα με κωδικοποίηση και γενικά η επεξεργασία των δεδομένων θα γίνει με τρόπο που θα καθιστά δυσχερή τον εντοπισμό/ταυτοποίηση των υποκειμένων των δεδομένων,
2.5. και με την προϋπόθεση ότι τα έντυπα συγκατάθεσης θα λαμβάνονται και θα τηρούνται ξεχωριστά από τα απαντημένα ανώνυμα ερωτηματολόγια
2.6. και αφού στο σημείο «Θ» έχετε περιλάβει μέτρα ασφάλειας και προστασίας των δεδομένων,
3. έχω οδηγίες να σας πληροφορήσω ότι η Γνωστοποίηση φαίνεται να είναι σύμφωνη με τις διατάξεις του άρθρου 7(1)(2) των περί Επεξεργασίας Δεδομένων Προσωπικού Χαρακτήρα (Προστασία του Ατόμου) Νόμων του 2001 μέχρι 2012 (Ν. 138(Ι)/2001 όπως τροποποιήθηκε με τους Ν. 37(Ι)/2003 και Ν. 105(Ι)/2012), στο εξής «ο Νόμος», και, ως εκ τούτου, έχει καταχωριστεί στο Μητρώο Αρχείων και Επεξεργασιών που τηρεί ο Επίτροπος δυνάμει των διατάξεων των άρθρων 7(4), 23(1)(ιγ) και 24(1)(α) του Νόμου.
4. Το πιο πάνω Μητρώο είναι προσβάσιμο στο κοινό, σύμφωνα με το άρθρο 24(2) του Νόμου.

(Μάριος Παπαχριστοδούλου)
για Επίτροπο Προστασίας Δεδομένων
Προσωπικού Χαρακτήρα

ΜΠαπ

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APPENDIX VI

ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ
ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ

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Αρ. Πρωτοκόλλου:0402/2017

7 Απριλίου 2017

Κυρία Κατερίνα Φιλίππου
Πειραιώς 2
2566, Λύμπια, Λευκωσία

Θέμα : Έρευνα με τίτλο: «Η κοινωνική στήριξη στη διαχείριση ασθενών με καρδιακή ανεπάρκεια και σακχαρώδη διαβήτη »

Έχω οδηγίες να αναφερθώ στο αίτημα σας για παραχώρηση άδειας διεξαγωγής της έρευνας σχετικά το πιο πάνω θέμα που υποβλήθηκε στην Επιστημονική Επιτροπή Προώθησης Ερευνών του Υπουργείου Υγείας, με ημερομηνία 24/2/2017 και να σας ενημερώσω ότι το αίτημα σας έχει **εγκριθεί** λαμβάνοντας υπόψη ότι έχει ήδη ληφθεί η συγκατάθεση των διευθυντών των νοσοκομείων , Διευθυντών των κλινικών και νοσηλευτικών λειτουργών που θα αναλάβουν την συλλογή των δεδομένων.

Σημειώνεται ότι το Υπουργείο Υγείας δεν φέρει οποιαδήποτε ευθύνη για την έκβαση των αποτελεσμάτων σας.

Νοείται ότι θα πρέπει να προβείτε σε ενημέρωση των προϊσταμένων των τμημάτων /υπηρεσιών για την διεξαγωγή της σχετικής έρευνας. Επισημαίνεται ότι σε καμία περίπτωση δεν θα πρέπει να διαταράσσεται η ομαλή λειτουργία των τμημάτων όπου θα διεξαχθεί η έρευνα.

Επίσης, με την ολοκλήρωση της έρευνάς σας θα πρέπει να παραδώσετε στην γραμματεία της επιτροπής τα ακόλουθα:

- Αντίγραφα ολοκληρωμένης έρευνας σε ηλεκτρονική και έντυπη μορφή
- Γραπτή συγκατάθεσή σας για την Διαχείριση των αποτελεσμάτων της έρευνας από το Υπουργείο Υγείας.
- Περίληψη της έρευνας σε συγκεκριμένη μορφή, καθώς και τα στοιχεία επικοινωνίας σας τα οποία θα αναρτούνται στην ιστοσελίδα του Υπουργείου Υγείας.

(Ειρήνη Γεωργίου)
για Γενική Διευθύντρια

Κοιν: ΠΛΥ
Αν. Διευθυντή ΙΥ&ΥΔΥ
Διευθυντή Νοσηλευτικών Υπηρεσιών

Υπουργείο Υγείας 1448 Λευκωσία
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APPENDIX VII

Systematic review and meta-analysis.

Heart, Lung and Circulation (2020) **29**, 1633–1647
1443-9506/20/$36.00
https://doi.org/10.1016/j.hlc.2020.04.019

REVIEW

Supportive Care Interventions to Promote Health-Related Quality of Life in Patients Living With Heart Failure: A Systematic Review and Meta-Analysis

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Sofia Ktisti, BSc, MSc [a], **Katerina Philippou, BSc, MSc** [b],
Ekaterini Lambrinou, BSc, MSc, PhD [b]

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Supportive care (physical, psychosocial, and spiritual) may be beneficial as a coping resource in the care of patients with heart failure (HF). Nurses may provide individualised supportive care to offer positive emotional support, enhance the patients' knowledge of self-management, and meet the physical and psychosocial needs of patients with HF. The aim of this study was to examine the potential effectiveness of supportive care interventions in improving the health- related quality of life (HRQoL) of patients with HF. Related outcomes of depression and anxiety were also examined. A systematic search of PubMed, CINAHL, and the Cochrane Library was performed to locate randomised controlled trials (RCTs) that implemented any supportive care interventions in patients with HF published in the English language. Identified articles were further screened for additional studies. Ten (10) RCTs were selected for the meta-analysis. Effect sizes were estimated between the comparison groups over the overall follow-up period, and presented along with confidence intervals (CIs). Statistical heterogeneity for each comparison was estimated using Q (chi square test) and I^2 statistics with 95% CIs. Statistical heterogeneity was observed in all study variables (i.e., HRQoL and dimensions). There was a positive, but not statistically significant, effect of social support on HRQoL (mean difference [MD], 5.31; 95% CI, −8.93 to 19.55 [p=0.46]). The results of the two dimensions suggested a positive and statistically significant effect of the supportive care interventions (physical: MD, 7.90; 95% CI, 11.31–4.50 [p=0.00]; emotional dimension: MD, 4.10; 95% CI, 6.14–2.06; [p=0.00]). The findings of the current study highlight the need to incorporate supportive care to meet the needs of patients with HF. Patients with HF have care needs that change continuously and rapidly, and there is a need of a continuous process in order to address the holistic needs of patients with HF at all times and not just in a cardiology department or an acute care setting. Patients with HF have multiple needs, which remain unmet. Supportive care is a holistic, ongoing approach that may be effective in identifying and meeting the care needs of patients with HF along with the patient. This review includes all interventions provided in individuals with HF, giving clinicians the opportunity to choose the most suitable ones in improving the clinical outcomes of their patients with HF.

Keywords Cardiovascular nursing • Heart failure • Meta-analysis • Quality of life • Supportive care

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Introduction

Patients with heart failure (HF) suffer from an incurable disease with an often-unpredictable trajectory [1,2]. The trajectory of HF is unique in terms of decline and death. It is typically characterised by a slow decline in physical capacities punctuated with serious exacerbations. The unpredictable illness often leads patients to become isolated and unable to make plans [3]. Physical symptoms, particularly breathlessness and fatigue, limit patients' ability to leave the house, leading them to become socially isolated [2,3]. Previous qualitative studies have reported social isolation, loneliness, and loss of friends as major contributors to the negative impact of the disease [3,4]. These physical, psychosocial (life-threatening illness, isolation), and spiritual factors may influence a person's health-related quality of life (HRQoL) in a number of ways, including declined physical strength, mood, impact on personal relationships (e.g., with their career), decreased well-being, and emotional distress [4]. Over the last few years, mortality has been improved owing to new therapeutic approaches. Nevertheless, patients still die from HF and are symptomatic in the last stage of their illness, highlighting the need for a holistic approach and care [5].

Although they often do not know much about their condition, patients with HF realise their poor prognosis owing to their experience of the symptoms of HF, particularly limitations such as shortness of breath, dizziness, and restrictions in activities of daily living [6]. Thus, they need someone to discuss their condition, concerns, and fears with [4,7]. However, they are not well informed about their prognosis or supported [4,7,8]. Patients often lack sufficient knowledge about their condition and prognosis. This is mostly due to poor communication between patients and health care providers [6]. They do not perceive HF as a life-limiting illness, even when they have knowledge of HF management [9,10].

Nurses may provide individualised supportive care to offer positive emotional support, enhance the patients' knowledge of self-management, and meet the physical and psychosocial needs of patients with HF via continuing assessment, counselling, and education [11]. Supportive care is a holistic view of disease management offered to all patients with a chronic or life-threatening illness [11]. Provisional planning, supporting patients in identifying unpredictable deteriorations in health status, and mitigating or reducing isolation and dependency that might co-occur, should be done, in part, by procuring available resources and support in advance [12,13].

Supportive care has a major role in positive, life-transforming change, and allows individuals to have a better positive HRQoL. The terms "palliative" and "supportive" care are often used interchangeably; however, there is a different definition for these two terms. A common goal is to improve the HRQoL of patients who have serious or life-threatening disease and provide them with support [12]. Supportive care is multidisciplinary holistic care provided to the patient and his/her family, from the time of diagnosis and throughout treatment with the aim of prolonging life expectancy and improving QoL, and into end-of-life care [13]. It is essential to clarify that palliative care is an important part of supportive care, mainly concerning the internal and psychosocial components of supportive care [14,15]. Supportive care includes modifying interventions in an effort to manage symptoms, and psychosocial or existential distress, and to identify strategies in order to cope with HF [16,17]. Supportive care is composed of four components: communication and decision-making; education; symptom management; and psychological and spiritual issues [5,16]. The aim of this systematic review and meta-analysis was to investigate the effectiveness of supportive care interventions in improving the HRQoL of patients with HF.

Aim of the Study

The present study examined the potential effectiveness of supportive care interventions in improving the HRQoL of patients with HF versus a control group. Based on the above framework, supportive care interventions were defined as all interventions referring to the four cited components: (1) communication (e.g., understand patient concerns and fears); (2) education (e.g., patient and family self-management [sodium, weight, and volume]); (3) psychosocial and spiritual issues (e.g., coping with illness); and (d) symptom management (e.g., HF medications for dyspnoea) [14]. The related outcomes of depression and anxiety were also examined. Supportive care interventions in all New York Heart Association stages were included, taking into consideration the trajectory of HF. The hypothesis was that supportive care interventions would have a positive effect on the HRQoL of patients with HF.

Methods

Design

A systematic review and meta-analysis were carried out assessing the effectiveness of supportive care interventions in patients with HF in terms of HRQoL and related outcomes (e.g., depression and anxiety). The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement checklist was used to conduct and report the meta-analysis [18].

Search Strategy

An electronic search of PubMed, CINAHL, and the Cochrane Library was conducted for articles published up to March 2017. Keywords used for the search were: "heart failure", "supportive care", "social support", and "social network" combined with the words "palliative care", "end of life stage", and "quality of life". The search strategy used was [(heart failure) AND supportive care OR social support OR social network] AND one of the keywords "palliative care", "end of life stage", "quality of life". The terms supportive care and palliative care are often used interchangeably in the literature. Hence, the study also included the term "palliative" in the search strategy. The "related articles" tool of PubMed was also used. The most relevant articles and reviews were manually searched for eligible studies.

Inclusion criteria

The inclusion criteria included English-language randomised controlled trial (RCT) results, measuring the outcome of HRQoL after supportive care interventions in HF, with regard to any component of support or setting. Articles were considered for inclusion if they included at least one of the four components of supportive care. Supportive care had to be provided simultaneously with usual care in an effort to manage symptoms, and psychosocial or existential distress, and to identify strategies in order to cope with HF. To enable comparability of the study findings, only studies that used the disease-specific tool Minnesota Living with Heart Failure Questionnaire (MLHFQ) to assess HRQoL were considered. The MLHFQ is one of the most comprehensive and widely used tools for measuring the HRQoL of patients with HF [19]. It has been translated into, and validated in, more than 25 languages. The original version included two subscales (physical and emotional); in some versions, a third subscale was added (social) [20].

Exclusion criteria

Articles matching with any of the following were not pooled: results of studies that calculated and presented patients' and relatives' HRQoL together as one population. Similarly, findings from pilot studies and unpublished research programs were not included.

Two (2) of the authors screened the titles of the retrieved articles and isolated potentially relevant ones. The eligibility of the relevant abstracts was examined separately by the two authors, who reviewed each article's abstract. The two authors used standard pretest selection forms independently to assess eligibility. A third author was involved, when needed, to reach consensus.

Data Extraction

One reviewer used data extraction forms to obtain the data of interest (e.g., methodology, setting, type of intervention, and statistical data with regard to the observed effect size). A second researcher reviewed the final data, to identify any extraction errors.

Quality Assessment

The methodological quality of the included trials was assessed by two authors using the CONSORT 2010 checklist. Eligible studies were assessed for their methodological quality. A "yes" or "no" answer was marked against each item based on whether the author had reported the variable or not. Two (2) independent reviewers evaluated the included studies against the checklist. Any conflicts among the reviewers were discussed and resolved, involving the third reviewer when necessary. The frequencies of positive answers are reported as percentages. The number of "positive answers" varied from 0 to 37.

Statistical Analysis

Data from each study were collected and meta-analysed using the Cochrane Library's Review Manager 5.3. Effect sizes were estimated between the comparison groups over the overall follow-up period, and presented along with confidence intervals (CIs). The overall pooled effect was estimated by the DerSimonian and Laird random-effects model in order to account for the observed heterogeneity between studies [19]. Statistical heterogeneity for each comparison was estimated using Q (chi square test) and I^2 statistics with 95% CIs. The main outcome was overall HRQoL among the control and intervention groups. Furthermore, estimates for a potential effect on the physical and emotional dimensions of the HRQoL were also calculated. Anxiety and depression were examined as secondary outcomes. For those two outcomes, the standardised mean difference (SMD) was used as a summary statistic in the current meta-analysis because different scales were used by the different research groups. For the three-arm study of Brodie et al. [21] and the four-arm study of Gary et al. [22], the arm that included all interventions was taken into consideration.

The heterogeneity of the studies was also estimated using funnel plots, while small study effects and/or publication bias were assessed by Egger's test. Owing to the small number of studies, subgroup analysis was not performed, but sensitivity analysis was undertaken to assess the extent to which the observed results were affected by excluding studies with uncharacteristic results versus the rest (e.g., [23]).

The association of different interventions (variables), including intensity and complexity of the intervention; duration, including behavioural therapy intervention; family support; and study design with the HRQOL, were also investigated, using meta-regression analysis.

Results

The search strategy revealed 499 studies. In total, 377 were excluded after examining the title and/or abstract. Three (3) studies were excluded because they were published in languages other than English. Moreover, 103 studies were excluded because they were reviews or meta-analyses. Six (6) studies were found to be duplicated. Finally, 10 studies were found to meet the inclusion criteria (Figure 1).

Overview of the RCTs

The trials were conducted in the following countries: Taiwan [24], Greece [25,26], Iran [27], Russia [23], Spain [28], the USA [22], the Netherlands [29], and the UK [21,30]. With the exception of two, the studies were of a single-centre nature [22–28,30]. The studies of Smeulders et al. [29] and Brodie et al. [21] were set in six and two hospitals, respectively. The duration of studies ranged from 8 weeks to 2 years (Table 1). The interventions used in the studies vary in intensity, complexity, and the intervention as such (Table 2).

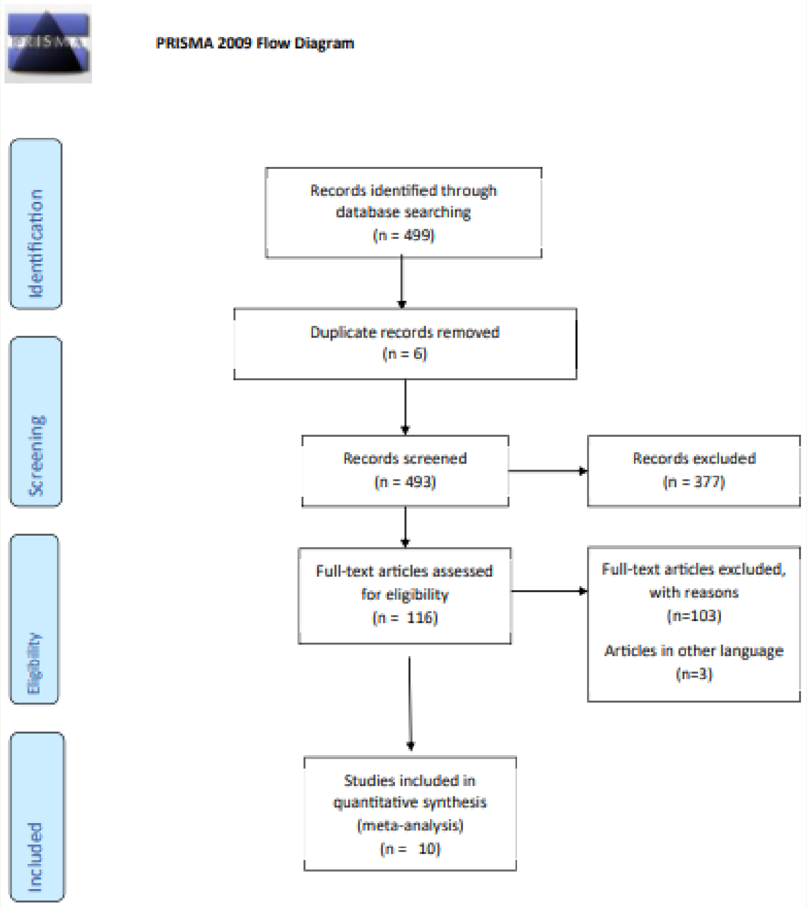


Figure 1 Study flowchart.
From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. https://doi.org/10.1371/journal.pmed1000097.

Methodological Quality of the RCTs

The eligible trials were assessed in terms of the 37 items of the most recent CONSORT statement [31].

Nine (9) trials reported more than half of the checklist items [21–28,32] and one reported 92% of them [29]. None of the articles reported all the important harms or unintended effects (for specific guidance, see CONSORT for harms [33]). The approach used in each study to estimate primary and secondary outcomes, results for each group, and the estimated effect size and its precision (such as 95% CI) were reported in nine (90%) articles [22–27,29,32]. Finally, 80% of all articles did not report the trial design (e.g., parallel or factorial), including allocation ratio [21–23,25–28,32]. Fifty per cent (50%) of all articles reported sources of funding and other support (such as supply of drugs), and the role of the funders [22–24,29,32].

Quantitative Data Synthesis

Statistical heterogeneity in all study variables is shown in Figure 2. Even though there was no statistical evidence of a small study bias, based on the Egger test for small-study effect (p=0.400), the small number of studies does not easily allow inference. In terms of the main outcomes there was evidence of high heterogeneity in all three components, as

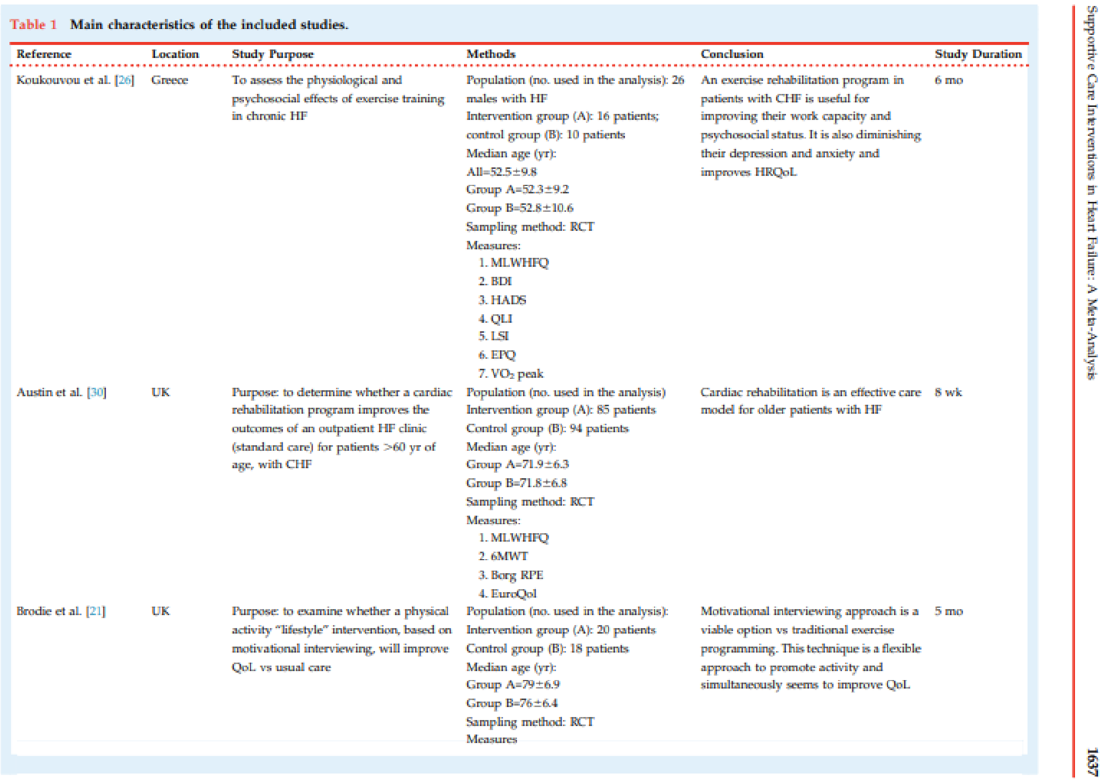


Table 1 Main characteristics of the included studies.

Reference	Location	Study Purpose	Methods	Conclusion	Study Duration
Koukouvou et al. [26]	Greece	To assess the physiological and psychosocial effects of exercise training in chronic HF	Population (no. used in the analysis): 26 males with HF Intervention group (A): 16 patients; control group (B): 10 patients Median age (yr): All=52.5±9.8 Group A=52.3±9.2 Group B=52.8±10.6 Sampling method: RCT Measures: 1. MLWHFQ 2. BDI 3. HADS 4. QLI 5. LSI 6. EPQ 7. VO_2 peak	An exercise rehabilitation program in patients with CHF is useful for improving their work capacity and psychosocial status. It is also diminishing their depression and anxiety and improves HRQoL.	6 mo
Austin et al. [30]	UK	Purpose: to determine whether a cardiac rehabilitation program improves the outcomes of an outpatient HF clinic (standard care) for patients >60 yr of age, with CHF	Population (no. used in the analysis) Intervention group (A): 85 patients Control group (B): 94 patients Median age (yr): Group A=71.9±6.3 Group B=71.8±6.8 Sampling method: RCT Measures: 1. MLWHFQ 2. 6MWT 3. Borg RPE 4. EuroQol	Cardiac rehabilitation is an effective care model for older patients with HF	8 wk
Brodie et al. [21]	UK	Purpose: to examine whether a physical activity "lifestyle" intervention, based on motivational interviewing, will improve QoL vs usual care	Population (no. used in the analysis): Intervention group (A): 20 patients Control group (B): 18 patients Median age (yr): Group A=79±6.9 Group B=76±6.4 Sampling method: RCT Measures	Motivational interviewing approach is a viable option vs traditional exercise programming. This technique is a flexible approach to promote activity and simultaneously seems to improve QoL.	5 mo

Table 1 (continued).

Reference	Location	Study Purpose	Methods	Conclusion	Study Duration
			1. MLWHFQ 2. SF-36 3. RTCR		
Smeulders et al. [29]	Netherlands	Purpose: to assess the effects of a chronic disease self-management program on psychosocial attributes, self-care behaviour, and QoL in HF patients who experienced slight-to-marked limitation of physical activity	Population (no. used in the analysis): Intervention group (A)=156 Control group (B)=109 Median age (yr): Group A=66.6±11 Group B=66.8±67.9 Sampling method: RCT Measures: 1. MLWHFQ 2. GSES 3. EHFScBS 4. RAND-36 5. KCCQ 6. HADS	Disease self-management program improved cognitive symptom management, self-care behaviour, and cardiac specific QoL	12 mo
Aguado et al. [28]	Spain	Purpose: to evaluate the effectiveness of a single home-based educational intervention for patients with HF	Population (no. used in the analysis): Intervention group (A)=14 Control group (B)=23 Median age (yr): Group A=77.8±8 Group B=77.4±6.8 Sampling method: RCT Measures: 1. MLWHFQ 2. BT 3. CI 4. PsSPMSQ 5. SF-36	Patients with HF who receive a home-based educational intervention experience fewer ED visits and unplanned readmissions with lower health care costs and improves QoL	24 mo
Andryukhin et al. [23]	Russia	Purpose: to estimate the impact of a structured, nurse-led patient education program and care plan in general practice on outcome parameters and events in patients with HF and preserved EF	Population (no. used in the analysis): Intervention group (A)=44 Control group (B)=41 Median age (yr): Group A=66.5±59–70 Group B=68±57–72	This disease-management program improved the patients' emotional status and QoL, positively influenced body weight, functional capacity, and attenuated heart remodelling	6 mo

Table 1 (continued).

Reference	Location	Study Purpose	Methods	Conclusion	Study Duration
			Sampling method: RCT Measures: 1. MLWHFQ 2. 6MWT 3. BMI 4. WC 5. HADS 6. BPLFBG 7. TC 8. LDL 9. CRP 10. NT-proBNP 11. CFA		
Gary et al. [22]	USA	Purpose: to assess the effectiveness of a combined 12-wk home-based exercise/ CBT program with CBT alone, exercise alone and with usual care in HF patients diagnosed with depression	Population (no. used in the analysis) Intervention group (A): 15 Control group (B): 14 Median age (yr): All patients=65.8±13.5 Sampling method: RCT Measures: 1. MLWHFQ 2. HAM-D 3. MINI 4. 6MWT	Interventions designed to improve both physical and psychological symptoms may provide the best method for optimising functioning and enhancing HRQoL in patients with HF	6 mo
Lakdizaji et al. [27]	Iran	Purpose: to examine the impact of a continuous training program on QoL of patients with HF	Population (no. used in the analysis) Intervention group (A)=22 Control group (B)=22 Median age (yr): Group A=62.8±9.5 Group B=60.6±9.5 Sampling method: RCT Measures: 1. MLWHFQ	Ongoing training programs can be effective in improving QoL of patients with HF. Applying an educational program as a nonpharmacological intervention can help to improve the QoL of HF patients	3 mo
Chrysohoou et al. [25]	Greece	Purpose: to evaluate the effect of high-intensity interval exercise on QoL and depression status in HF patients	Population (no. used in the analysis) Intervention group (A)=33 Control group (B)=39 Median age (yr):	High-intensity exercise program seems to offer beneficial effects haemodynamic, clinical factors, and QoL, improving the ability to perform daily activities	12 wk

Table 1 (continued).

Reference	Location	Study Purpose	Methods	Conclusion	Study Duration
			Group A=63±9 Group B=56±11 Sampling method: RCT Measures: 1. MLWHFQ 2. ZDRS 3. IPAQ 4. 6MWT 5. VO_{2max} 6. VCO_{2max}		
Wang et al. [24]	Taiwan	Purpose: to investigate the effects of a supportive educational nursing care program on fatigue and quality of life in patients with HF	Population (no. used in the analysis) Intervention group (A)=47 Control group (B)=45 Median age (yr): Group A=63.26±6.18 Group B=68.33±11.53 Sampling method: RCT Measures: 1. MLWHFQ 2. PFS 3. SDI 4. HADS 5. MSPSS	The supportive educational nursing care program alleviates fatigue and improves QoL in patients with HF	12 wk

Abbreviations: HF, heart failure; RCT, randomised controlled trial; MLWHFQ, Minnesota Living With Heart Failure Questionnaire; BDI, Beck Depression Inventory; HADS, Hospital Anxiety and Depression Scale; QLI, Quality of Life Index; LSI, Scale of Life Satisfaction; EPQ, Eysenck Personality Questionnaire; VO_2, oxygen uptake; CHF, chronic heart failure; HRQoL, health-related quality of life; 6MWT, 6 min walking test; RPE, Borg scale rating of perceived exertion; SF-36, medical outcomes short form-36 health survey; RTCR, Readiness-to-change ruler; GSES, General Self-efficacy Scale; EHFScBS, European Heart Failure Self-Care Behaviour Scale; RAND-36, RAND 36-item Health Survey; KCCQ, Kansas City Cardiomyopathy Questionnaire; BT, Barthel test; CI, Charlson index; PsSPMSQ, Spanish version of Pfeiffer's Short Portable Mental Status Questionnaire; ED, Emergency Department; EF, ejection fraction; BMI, body mass index; WC, waist circumference; BPLFBG, blood plasma levels of fasting blood glucose; TC, total cholesterol; LDL, low-density lipoprotein; CRP, C-reactive protein; NT-proBNP, N-terminal pro-brain natriuretic peptide; CFA, cardiac function assessment; CBT, cognitive behavioural therapy; HAM-D, Hamilton Rating Scale for Depression; MINI, Mini International Neuropsychiatric Interview; ZDRS, Greek language Zung Depression Rating Scale; IPAQ, International Physical Activity Questionnaire; VO_{2max}, maximal oxygen uptake; VCO_{2max}, maximal carbon dioxide production; PFS, Piper fatigue scale; SDI, symptomatic distress index; MSPSS, multidimensional scale of perceived social support.

Table 2 **Intervention and delivery of the intervention of included studies.**

Reference	Intervention	Delivery of the Intervention
Koukouvou et al. [26]	A 6-mo supervised exercise training program gradually modified by the patients' perceived exertion and adaptation to the training prescription. Three months of aerobic training and then resistance exercises with therabands and small weights. Psychological testing performed before starting the exercise program	Exercise program: not mentioned Psychological testing: by a physician
Austin et al. [30]	An 8-wk cardiac rehabilitation program. Patients attended classes twice weekly for a period of 2.5 hr. Patients graduated from the program to a 16-wk community-based care regimen consisting of weekly 1-hr exercise sessions. During the first 8 wk of the trial, patients received additional education input, during weekly group sessions, on a variety of essential topics (medication, diet, exercise). If required, patients and their partners also received individual counselling from the dietician, psychotherapist, and occupational therapist	Rehabilitation program: clinical nurse specialist Education and counselling: multidisciplinary team (physician, nurse, dietician, psychotherapist, and occupational therapist)
Brodie et al. [21]	Provision of information and recommendations to increase physical activity, including details of options available locally to access such opportunities. Motivational intervention comprised eight, 1-hr home-based sessions, delivered weekly. Sessions concentrated on how to increase energy expenditure by the integration of physical activities into patients' daily routines	Physical activity recommendations: experienced HF specialist nurse Motivational intervention: the researcher who had no clinical qualifications
Smeulders et al. [29]	A structured self-management program consisted of six weekly group sessions of 2.5 hr each. The program incorporates four strategies to enhance self-efficacy expectancies: skills mastery (goal-setting and action planning); re-interpretation of symptoms (cognitive symptom-management techniques and deals with relieving symptom problems); modelling; and social persuasion (motivation of patients to change their behaviours and beliefs)	All classes were led by a cardiac nurse specialist ("professional leader") and a patient with HF ("peer leader"), both trained in the protocol
Aguado et al. [28]	The intervention consisted of a visit by a trained nurse to patients in their homes 1 wk after discharge. The visit lasted 2 hr and patients educated about self-management (e.g., medication adherence), habits (e.g., fluid intake, salt-free diet), and preventive activities (e.g., designed for therapy and physical activity). Periodic meetings were attended by the doctor and nurses to solve problems arising in the home visits, to perfect education skills, and to control the fulfillment of the educational protocol	Educational intervention: trained nurse
Andryukhin et al. [23]	An educational program consisting of four weekly educational group sessions, targeting individual lifestyle changes and modifications of cardiovascular risk factors (month 1). Each session lasted about 90 min and included a lecture and a practical skills session. Exercise training: four weekly introductory sessions of 30 min each (first month). An individualised program was recommended for further practice at home during the next 5 mo (months 2–6). Proactive and supportive care program: included weekly 15–30 min consultations in the health centre or by phone over 5 mo (lifestyle changes, checked medication compliance, and elicited information about any changes in the condition of the patient) (months 2–6)	Educational program and supportive care program: specially trained nurses Exercise training: a physiotherapist who had been trained in the study protocol
Gary et al. [22]	Exercise program: 12 weekly face-to-face home visits to monitor walking progress. • Researchers educated the patient on the rationale for exercise in HF; • Instructed on self-monitoring of symptoms during walking; • Provided the patient with a monitor and instruction on how to use it; • Provided patient with exercise logs and instructions; • Instructed on use of the 6–20-point Borg's rate of perceived exertion scale; • Provided patient with blood pressure cuff and weight scale; • Observed participant response to walking outside the home.	Research nurse: exercise program CBT intervention: psychiatric clinical nurse specialists or clinical psychology doctoral students

Table 2 **(continued).**

Reference	Intervention	Delivery of the Intervention
	CBT The first 2–3 sessions were used to: • build and establish rapport with the patient; • review principles of the cognitive model (agenda, thoughts, influence, behaviour); • educate the patient about depression; • teach the patient about CBT methods that may be used (i.e., identifying automatic thoughts, activity scheduling); • establish mutual collaborative goals for therapy; • clarify concerns and answer any questions about CBT. Depressive symptoms were monitored weekly using mood-rating charts.	
Lakdizaji et al. [27]	The intervention group first received one-to-one meeting to introduce the objectives of study, content of the program, and talk about educational needs of participants. At the first appointment, each patient in the intervention group was given a booklet, entitled "How can I learn to live with heart failure" based on modules (HF, low-salt regimen, medicines, self-care, physical activity, feelings, tips for family), provided by the researcher. Then, a home meeting happened every 3 wk, took approximately 1 hr to review previous goals and progression toward goals. To ensure compliance between meetings, phone calls were made to answer patients' questions in the intervention group	Not mentioned
Chrysohoou et al. [25]	High-intensity intermittent aerobic training. The training consisted of 45 min/d, 3 d/wk for 12 consecutive wk. Total period of 12 wk	Not mentioned
Wang et al. [24]	A 12-wk supportive educational nursing care program consisting of three parts: fatigue assessment and monitoring; fatigue management education; and outcome evaluation. Participants in the intervention group received four face-to-face education and counselling interventions performed by the researchers at the first visit and 4, 8, and 12 wk after the first visit at a meeting room. Each face-to-face education and counselling intervention was about 30 min. During the intervention, the researchers performed nursing assessment, education, and counselling, and provided emotional support to patients	The intervention was delivered by one of the authors who was a senior cardiovascular nurse and was familiar with the interventions

Abbreviations: CBT, cognitive behavioral therapy; HF, heart failure.

indicated by both the Q test and I^2 statistics: overall score (χ^2=64.64, I^2=86%, p=0.002), and physical (χ^2=176.99, I^2=97%, p=0.02) and emotional dimensions (χ^2=61.10, I^2=92%, p=0.02).

Quantitative data synthesis using the funnel plots showed asymmetry and high statistical heterogeneity between the studies. The study of Lakdizaji et al. [27] was found to have the largest positive effect of all study outcomes, which was rather uncharacteristic compared to the rest of the studies. The study of Andryukhin et al. [23] did not follow normal distribution; hence, it was decided to exclude both studies from a sensitivity analysis, which did not affect the overall conclusion (Figure 4).

HRQoL of Patients with HF Receiving Supportive Care Versus Usual Care

The main study outcome was the effect of supportive care interventions in patients with HF in terms of overall HRQoL, based on the MLHFQ. All included studies examined the overall score of the tool, and six studies [23,24,26,27,29,32] also assessed the two subscales (physical and emotional dimensions). The observed overall effect indicated a positive effect of supportive care on HRQoL, and was statistically significant (SMD, −9.44; 95% CI, −15.54 to −3.33; p=0.002) (Figure 3). A sensitivity analysis excluding the studies of Andryukhin et al. [23] and Lakdizaji et al. [27] was performed. The former did not follow normal distribution and the latter had different outcomes compared to the other studies. After the exclusion of those two studies the effect of supportive care interventions versus standard care remained positive and statistically significant (SMD, −5.84; 95% CI, −11.55 to −0.13; p=0.05). The results of the two dimensions of the MLHFQ suggest a positive and statistically significant effect of the supportive care interventions (physical: SMD, −6.95 [95% CI, 12.78 to −1.11; p=0.02 [Figure 5]]; emotional dimension: SMD, −3.64 [95% CI, −6.34 to −0.93; p=0.00 [Figure 6]]).

Depression and Anxiety

Depression and anxiety were examined in five [22–25,29] and three [23,24,29] studies, respectively. Even though

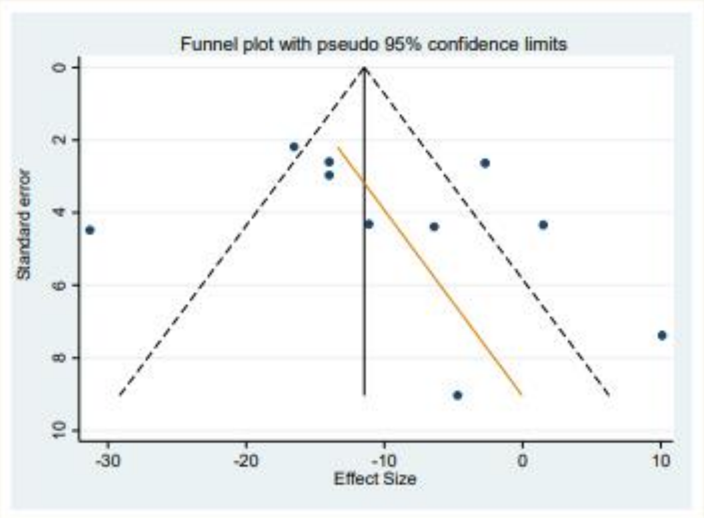
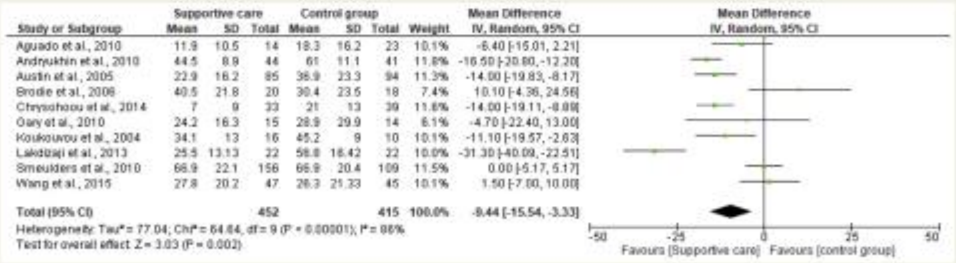


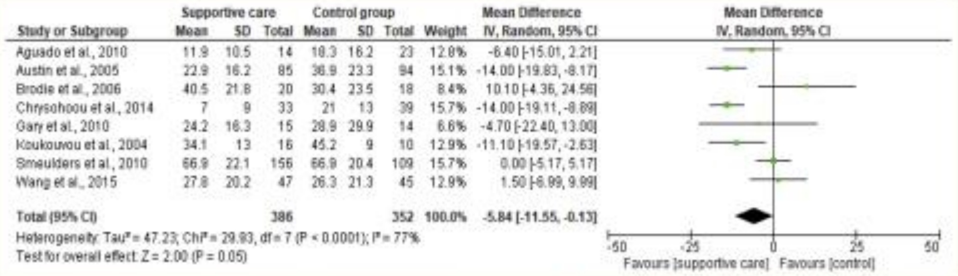
Figure 2 Funnel plot of included studies.



Study or Subgroup	Supportive care Mean	SD	Total	Control group Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Aguado et al., 2010	11.9	10.5	14	18.3	16.2	23	10.1%	-6.40 [-15.01, 2.21]
Andryukhin et al., 2010	44.5	8.9	44	61	11.1	41	11.8%	-16.50 [-20.80, -12.20]
Austin et al., 2005	22.9	16.2	85	36.9	23.3	94	11.3%	-14.00 [-19.83, -8.17]
Brodie et al., 2006	40.5	21.8	20	30.4	23.5	18	7.4%	10.10 [-4.36, 24.56]
Chrysohoou et al., 2014	7	9	33	21	13	39	11.6%	-14.00 [-19.11, -8.89]
Gary et al., 2010	24.2	16.3	15	28.9	29.9	14	6.1%	-4.70 [-22.40, 13.00]
Koukouvou et al., 2004	34.1	13	16	45.2	9	10	10.1%	-11.10 [-19.57, -2.63]
Lakdizaji et al., 2013	25.5	13.13	22	56.8	16.42	22	10.0%	-31.30 [-40.09, -22.51]
Smeulders et al., 2010	66.9	22.1	156	66.9	20.4	109	11.5%	0.00 [-5.17, 5.17]
Wang et al., 2015	27.8	20.2	47	26.3	21.33	45	10.1%	1.50 [-7.00, 10.00]
Total (95% CI)			452			415	100.0%	-9.44 [-15.54, -3.33]

Heterogeneity: $Tau^2 = 77.04$; $Chi^2 = 64.64$, df = 9 ($P < 0.00001$); $I^2 = 86\%$
Test for overall effect: Z = 3.03 (P = 0.002)

Figure 3 Forest plot of comparison. Quality of life, outcome: MLWHFQ total score.
Abbreviations: SD, standard deviation; CI, confidence interval; MLWHFQ, Minnesota Living with Heart Failure Questionnaire.



Study or Subgroup	Supportive care Mean	SD	Total	Control group Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Aguado et al., 2010	11.9	10.5	14	18.3	16.2	23	12.8%	-6.40 [-15.01, 2.21]
Austin et al., 2005	22.9	16.2	85	36.9	23.3	94	15.1%	-14.00 [-19.83, -8.17]
Brodie et al., 2006	40.5	21.8	20	30.4	23.5	18	8.4%	10.10 [-4.36, 24.56]
Chrysohoou et al., 2014	7	9	33	21	13	39	15.7%	-14.00 [-19.11, -8.89]
Gary et al., 2010	24.2	16.3	15	28.9	29.9	14	6.6%	-4.70 [-22.40, 13.00]
Koukouvou et al., 2004	34.1	13	16	45.2	9	10	12.9%	-11.10 [-19.57, -2.63]
Smeulders et al., 2010	66.9	22.1	156	66.9	20.4	109	15.7%	0.00 [-5.17, 5.17]
Wang et al., 2015	27.8	20.2	47	26.3	21.3	45	12.9%	1.50 [-6.99, 9.99]
Total (95% CI)			386			352	100.0%	-5.84 [-11.55, -0.13]

Heterogeneity: $Tau^2 = 47.23$; $Chi^2 = 29.93$, df = 7 ($P < 0.0001$); $I^2 = 77\%$
Test for overall effect: Z = 2.00 (P = 0.05)

Figure 4 Sensitivity analysis: outcome quality of life score (excluding [23] and [27]).
Abbreviations: SD, standard deviation; CI, confidence interval.

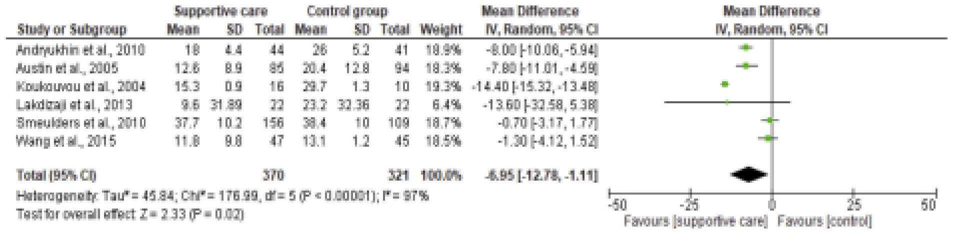


Figure 5 Forest plot of comparison. Quality of life/physical dimension, outcome: physical dimension/quality of life.
Abbreviations: SD, standard deviation; CI, confidence interval.

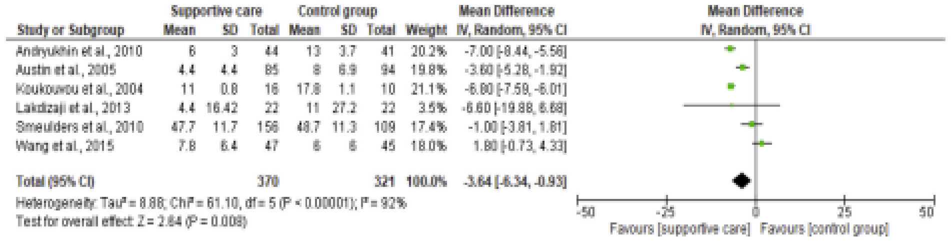


Figure 6 Forest plot of comparison. Quality of life outcome: emotional dimension/quality of life.
Abbreviations: SD, standard deviation; CI, confidence interval.

tools other than the MLHFQ were used, it was decided to meta-analyse the data, as depression and anxiety are very important factors in HF. Supportive care was found to have positive effect in depression (SMD −0.53; 95% CI, −1.23 to 0.16 [p=0.13]) and anxiety (SMD −0.83; 95% CI, −3.40 to 1.73 [p=0.53]) (Figures 6 and 7), but was not statistically significant for either outcome, at least at the 5% level.

Meta-Regression

To further understand the results of the meta-analysis, a meta-regression analysis was performed using Stata (StatCorp, College Station, TX, USA), which revealed that two of the undertaken variables, family support and behavioural therapy, were related to the effect size of the studies. Paradoxically, those two variables were found to have an inverse relation with the effectiveness of the intervention regarding HRQoL.

Meta-regression also showed that studies with higher baseline tend to find larger effects than those with lower baseline levels. Similarly, studies in which participants were more similar also tend to find larger effects. Both findings were found to be statistically significant (Table 3).

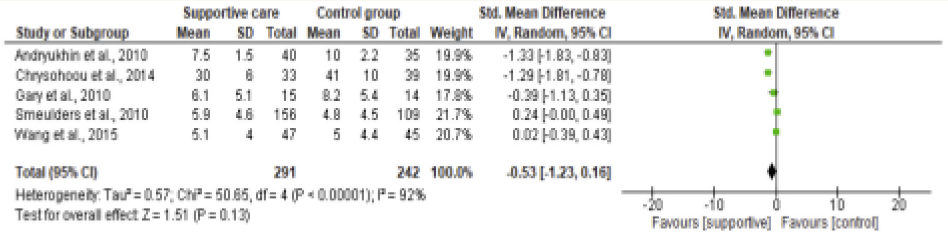


Figure 7 Forest plot of comparison. Quality of life outcome: depression.
Abbreviations: SD, standard deviation; CI, confidence interval.

Table 3 Explanation of the meta-regression findings for the variables of behavioral therapy and family.

	Coefficient	Standard Error	p>I z I
Behavioural	10.63818	6.763371	0.116
Family	18.99095	8.950608	0.034
_Cons	−11.1293	9.882136	0.260
	Coef.	**St. Error**	**p>I z I**
Baseline	9.599226	4.72426	0.042
Variance	−11.99298	4.698562	0.011
_Cons	10.05473	4.216793	0.017

Discussion

The objective of this systematic review and meta-analysis of randomised control trials was to examine the effectiveness of supportive care interventions on the HRQoL of patients with HF. A comprehensive search of the literature yielded 10 studies fulfilling the predefined inclusion criteria.

The overall pooled effect between patients receiving supportive care was found to be positive and statistically significant (Figure 3), as the effect on the two dimensions, physical and emotional, were found to be smaller than the total score but statistically significant (Figures 5 and 6). Quality of life is a subjective measure of the positive and negative aspects of personal life experience and is a multidimensional concept, including physical health, psychological health, social relationships, and environmental aspects [34]. Our findings are supported by other studies that have indicated that supportive care has positive effects on the HRQoL of patients with HF [35–37].

Fitzsimons and Strachan [38] also state that physical and emotional health are the most challenging care needs of patients with HF. The focus changes from "cure" to "care". This includes any distressing symptoms, promoting the best possible quality of life by providing support to families. This kind of care might be different from the "usual cardiology care" and cardiology needs. It expands the traditional medical goals to help patients and their families to cope with the unpredictable [1].

Depression and anxiety are important related outcomes for patients with HF. In this study the effect of the supportive care interventions was found to be positive, but not statistically significant (Figures 7 and 8). Other studies also reported that supportive care has positive effects on depression and anxiety [22,39,40]. The study of Chang et al. [41], which had as a primary outcome the effects of a supportive care on anxiety and depression, highlights that the effectiveness of the intervention results from tailored, individualised educational sessions, provision of a manual, a video, and follow-up telephone counselling. Thus, the significance of the effectiveness of each intervention on anxiety and depression may relate to the degree of provision of those variables.

Supportive care in patients with HF is a new approach for cardiology nurses [4]. Even though there is evidence of effective interventions [20,42], there is no systematic design of supportive interventions that might be comparable with each other. This may be due to the trajectory of HF, which is characterised by exacerbations of symptoms requiring acute and intensive care [43]. However, at some point, rescue attempts fail and death may appear to be "sudden" or unexpected [11]. This may also differentiate supportive care for patients with HF. After discharge, patients may go home in either the same health condition, or a little bit worse, and return to their usual activities. At this point they need supportive care to keep them stable and at the same time prepare them for the next acute event, which may be death. Supportive care plays an important role in positive, life-transforming change and allows individuals to have a more positive HRQoL. Improved HRQoL, as defined by patients and their family, is as much the goal as any reduction in mortality [40].

As mentioned above there is no standardised supportive care. Thus, the large statistical heterogeneity observed in the current meta-analysis might be suggestive of true "methodological" and "clinical heterogeneity", both in terms of the type of interventions employed, as well as the settings and patient characteristics. Interventions used varied in intensity, design, and intervention as such. For example, in one study, the effect of intervention on fatigue and HRQoL was assessed over a 12-week follow-up period [24] and over 6 months in another study [23]. Another example is a study's sample size. Koukouvou et al. [26] assessed 26 male patients with HF, a small proportion of eligible patients. The study of Brodie et al. [21] found that the target of 274 patients was not completely reached (n=265; 97%), which slightly decreases the power of the trial to find long-term effects.

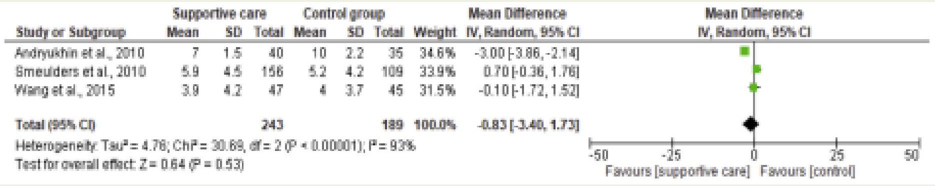


Figure 8 Forest plot of comparison. Quality of life outcome: anxiety.
Abbreviations: SD, standard deviation; CI, confidence interval.

The meta-regression revealed two variables, behavioural therapy and family support, to have an inverse relation with the effectiveness of the intervention regarding HRQoL. This outcome supports the results of the study by Durante et al. [44], who suggest caregivers be educated and given formal information. Often caregivers do things "incorrectly" because they do not know the right way to do it [45], or caregivers' mental and psychological health does not allow them to do it efficiently [45–47]. As far as behavioural therapy is concerned, even though it is found to be effective, further research is needed in order to clarify the long-term effects on HF outcomes [46]. The result may be further explained by the large heterogeneity between interventions and the variability of the populations participating.

Recent data show a close relationship between caregivers' strain, mental health, psychosocial status, and support, and it is suggested that caregivers need supportive care [45], which is why researchers suggest that supporting caregivers has an ethical and clinical rationale as well [45,46,48,49]. Decreasing family distress is a key to improving patient physical and mental quality of life [36]. Studies included in the current review refer in interventions focussing only on patients, even though the care of patients with a chronic illness depends on caregivers, which might be an explanation for the negative relationship found. Only two studies measured support or involved family in obtaining data, but the intervention was only for the patients. The finding is enlightening for researchers and clinicians developing HF management programs and supportive care interventions.

The heterogeneity of the findings regarding the effectiveness of behavioural therapy may be attributable to varying trial designs, intervention components, follow-up periods, or outcome assessments A recent, large systematic review and meta-analysis found that there are no effects of self-management (behavioural therapy) interventions on general outcomes, such as quality of life, in contrast to specific to HF-related outcomes (e.g., re-admission) [50]. The intervention must be customised, based on the needs of each patient, and along the mechanism that will be effective.

The main mechanisms of HF disease-management programs are associated with increased patient understanding of HF and self-care, more involvement of caregivers and family members in this self-care, enhanced self-efficacy and psychological well-being [51], increased support from health professionals, and ease of use of technology. These main mechanisms do not operate alone but require favourable contextual factors to be present [50,52]. Individualised patient-centred care should be addressed and managed taking into consideration the environment of the patients and the caregivers on whom they count [37,45,50].

There are also differences, mostly cultural, on how people perceive support and view themselves and relationships [53]. Supportive care may be effective when it takes a form that responds to someone's expectations based in a particular culture [54].

The results of the current review and meta-analysis may be ambiguous in terms of the overall effect of the supportive care interventions but certainly provide information on the need of a new approach to care in patients with HF, who have supportive care needs that change continuously and rapidly. These needs reflect the human entity, which is less medical, but provides comfort to the person. The holistic needs of patients with HF have to be addressed continuously and not only in a cardiology department or in an acute care setting [46,50].

Strengths and Limitations

We have thoroughly reviewed the effectiveness of supportive care in HF, providing HF nurses and allied professionals the opportunity to consider different approaches and interventions when developing HF management programs. It also provides an opportunity to compare interventions to see which is more effective and adaptable. Of course, this also creates the limitation that a small number of studies have been identified with a large statistical heterogeneity.

Conclusions

The current meta-analysis provides information on how supportive care interventions may affect HRQoL. However, the optimal characteristics of successful and structured supportive care interventions remain undetermined and more studies are needed for this task. The findings of the current study highlight the need to incorporate supportive care interventions to meet holistically the needs of patients with HF. The care needs of patients with HF remain unaddressed.

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APPENDIX VIII

“ζω
με την
καρδιακή
ανεπάρκεια”

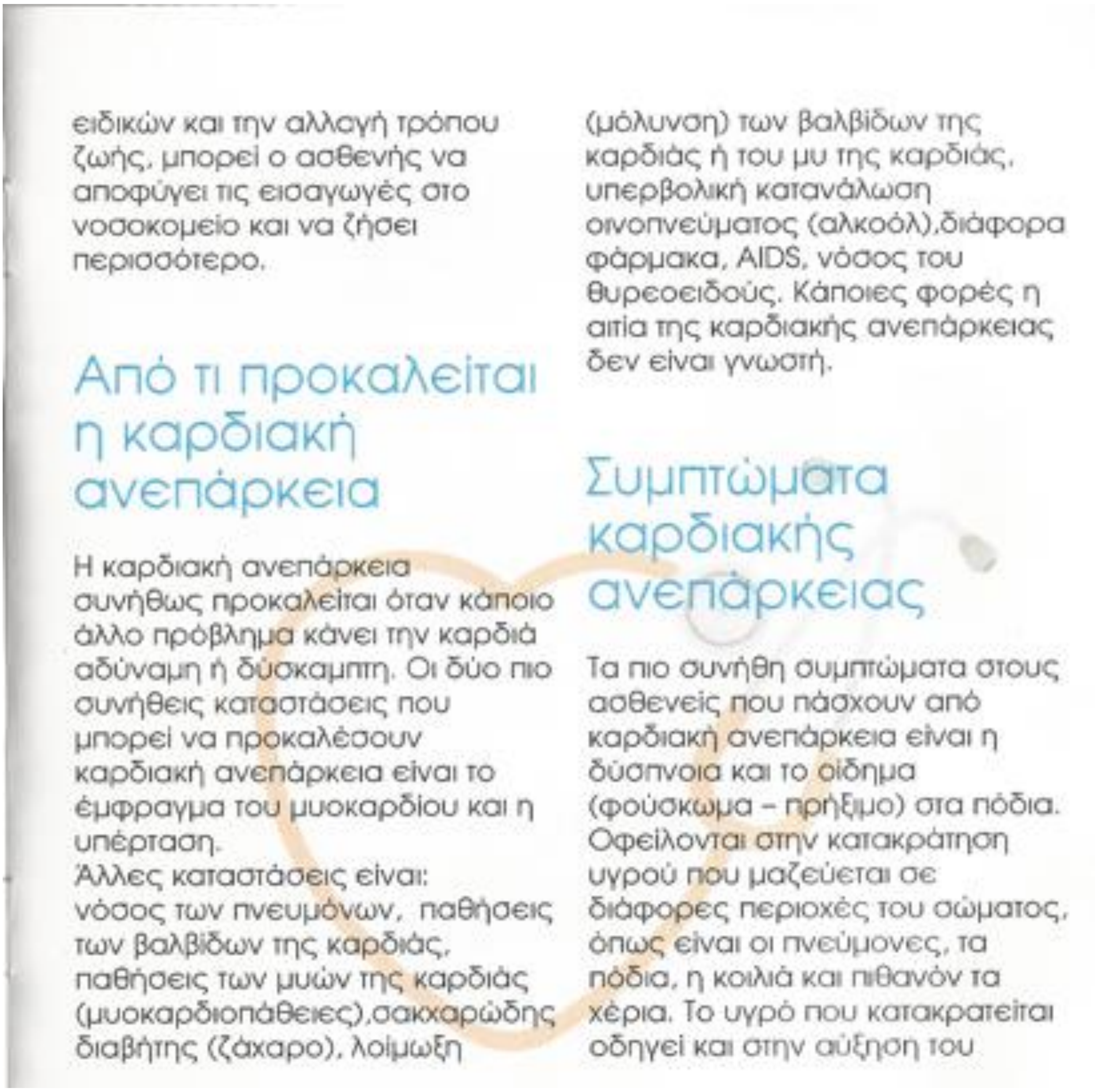
Η φυσιολογική λειτουργία της καρδιάς

Η καρδιά είναι ένας μυς που προωθεί το αίμα σε όλο το σώμα, δηλαδή λειτουργεί όπως μια αντλία. Ένα ηλεκτρικό σήμα διεγείρει τα τοιχώματα της καρδιάς προκαλώντας τη σύσπασή τους. Με τη σύσπαση αυτή, το αίμα προωθείται στην κυκλοφορία και μεταφέρει οξυγόνο και θρεπτικά συστατικά στους ιστούς και παράλληλα απομακρύνει τις άχρηστες ουσίες. Ο ρυθμός της καρδιακής λειτουργίας ποικίλει ανάλογα με την κατάσταση στην οποία βρίσκεται ο οργανισμός.

Ο καρδιακός ρυθμός αυξάνει κατά την άσκηση και μειώνεται στην ηρεμία. Σε περιπτώσεις κατά τις οποίες οι ιστοί χρειάζονται περισσότερο οξυγόνο ή θρεπτικά συστατικά (πχ πυρετός), τότε η καρδιά προσαρμόζεται αυξάνοντας το ρυθμό της, ανταποκρινόμενη στις αυξημένες ανάγκες του οργανισμού.

Χρόνια καρδιακή ανεπάρκεια

Κάποιος που έχει διαγνωστεί με τη νόσο, όταν ακούσει τον όρο καρδιακή ανεπάρκεια, μπορεί να σκεφτεί ότι η καρδιά του σταμάτησε να χτυπά και ότι πρόκειται να πεθάνει. Στην πραγματικότητα αυτό που συμβαίνει είναι ότι ο καρδιακός μυς έχει εξασθενήσει και δεν μπορεί να ανταποκριθεί πλήρως στην ανάγκες του οργανισμού. Η καρδιά, είτε δε γεμίζει αρκετά με αίμα, είτε δεν προωθεί με αρκετή δύναμη το αίμα στο σώμα ή και τα δύο. Το αποτέλεσμα είναι η καρδιά να αδυνατεί να τροφοδοτήσει με αίμα τα διάφορα όργανα και να ικανοποιήσει τις ανάγκες τους σε οξυγόνο. Μια ορισμένη ποσότητα αίματος που δεν προωθείται αποτελεσματικά από την καρδιά στον οργανισμό, συσσωρεύεται στα αγγεία γύρω από τους πνεύμονες, με αποτέλεσμα κάποιες φορές υγρό από τα αγγεία να διαπερνά τα τοιχώματα του πνεύμονα. Όταν συμβαίνει αυτό έχουμε μια κατάσταση η οποία ονομάζεται «Πνευμονικό οίδημα» και χαρακτηρίζεται από δύσπνοια. Η καρδιά που δεν μπορεί να ικανοποιήσει τις ανάγκες των ιστών σε οξυγόνο, αναγκάζεται να χτυπά με πιο γοργό ρυθμό, για να στέλνει πιο πολύ αίμα στο σώμα κάθε λεπτό. Παράλληλα αυξάνει σε μυϊκή μάζα (υπερτροφία) για να δουλεύει με πιο πολύ δύναμη. Αυτό προοδευτικά, επιβαρύνει επιπλέον την καρδιά. Πρόκειται για μια χρόνια, σοβαρή νόσο, αλλά με τη σωστή φαρμακευτική αγωγή, την προσεχτική διαχείριση, με τη συμμόρφωση στις οδηγίες του γιατρού και των



ειδικών και την αλλαγή τρόπου ζωής, μπορεί ο ασθενής να αποφύγει τις εισαγωγές στο νοσοκομείο και να ζήσει περισσότερο.

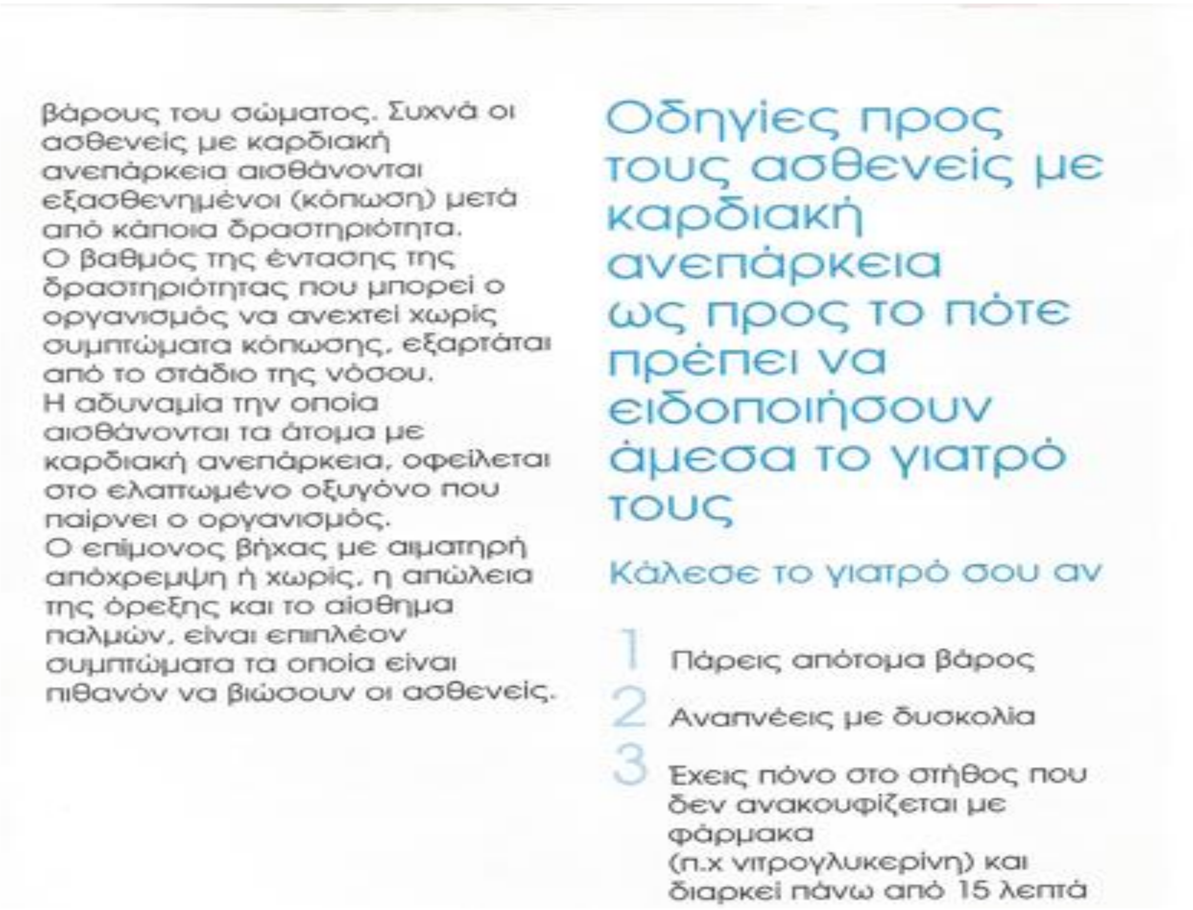
Από τι προκαλείται η καρδιακή ανεπάρκεια

Η καρδιακή ανεπάρκεια συνήθως προκαλείται όταν κάποιο άλλο πρόβλημα κάνει την καρδιά αδύναμη ή δύσκαμπτη. Οι δύο πιο συνήθεις καταστάσεις που μπορεί να προκαλέσουν καρδιακή ανεπάρκεια είναι το έμφραγμα του μυοκαρδίου και η υπέρταση.

Άλλες καταστάσεις είναι:
νόσος των πνευμόνων, παθήσεις των βαλβίδων της καρδιάς, παθήσεις των μυών της καρδιάς (μυοκαρδιοπάθειες),σακχαρώδης διαβήτης (ζάχαρο), λοίμωξη (μόλυνση) των βαλβίδων της καρδιάς ή του μυ της καρδιάς, υπερβολική κατανάλωση οινοπνεύματος (αλκοόλ),διάφορα φάρμακα, AIDS, νόσος του θυρεοειδούς. Κάποιες φορές η αιτία της καρδιακής ανεπάρκειας δεν είναι γνωστή.

Συμπτώματα καρδιακής ανεπάρκειας

Τα πιο συνήθη συμπτώματα στους ασθενείς που πάσχουν από καρδιακή ανεπάρκεια είναι η δύσπνοια και το οίδημα (φούσκωμα – πρήξιμο) στα πόδια. Οφείλονται στην κατακράτηση υγρού που μαζεύεται σε διάφορες περιοχές του σώματος, όπως είναι οι πνεύμονες, τα πόδια, η κοιλιά και πιθανόν τα χέρια. Το υγρό που κατακρατείται οδηγεί και στην αύξηση του



βάρους του σώματος. Συχνά οι ασθενείς με καρδιακή ανεπάρκεια αισθάνονται εξασθενημένοι (κόπωση) μετά από κάποια δραστηριότητα.
Ο βαθμός της έντασης της δραστηριότητας που μπορεί ο οργανισμός να ανεχτεί χωρίς συμπτώματα κόπωσης, εξαρτάται από το στάδιο της νόσου.
Η αδυναμία την οποία αισθάνονται τα άτομα με καρδιακή ανεπάρκεια, οφείλεται στο ελαττωμένο οξυγόνο που παίρνει ο οργανισμός.
Ο επίμονος βήχας με αιματηρή απόχρεμψη ή χωρίς, η απώλεια της όρεξης και το αίσθημα παλμών, είναι επιπλέον συμπτώματα τα οποία είναι πιθανόν να βιώσουν οι ασθενείς.

Οδηγίες προς τους ασθενείς με καρδιακή ανεπάρκεια ως προς το πότε πρέπει να ειδοποιήσουν άμεσα το γιατρό τους

Κάλεσε το γιατρό σου αν

1. Πάρεις απότομα βάρος
2. Αναπνέεις με δυσκολία
3. Έχεις πόνο στο στήθος που δεν ανακουφίζεται με φάρμακα (π.χ νιτρογλυκερίνη) και διαρκεί πάνω από 15 λεπτά

4 Ξύπνησες το βράδυ και δεν μπορούσες να πάρεις ανάσα

5 Νιώθεις υπερβολική κόπωση

6 Έχεις επιδεινούμενο φούσκωμα - πρήξιμο

7 Έχεις απώλεια όρεξης

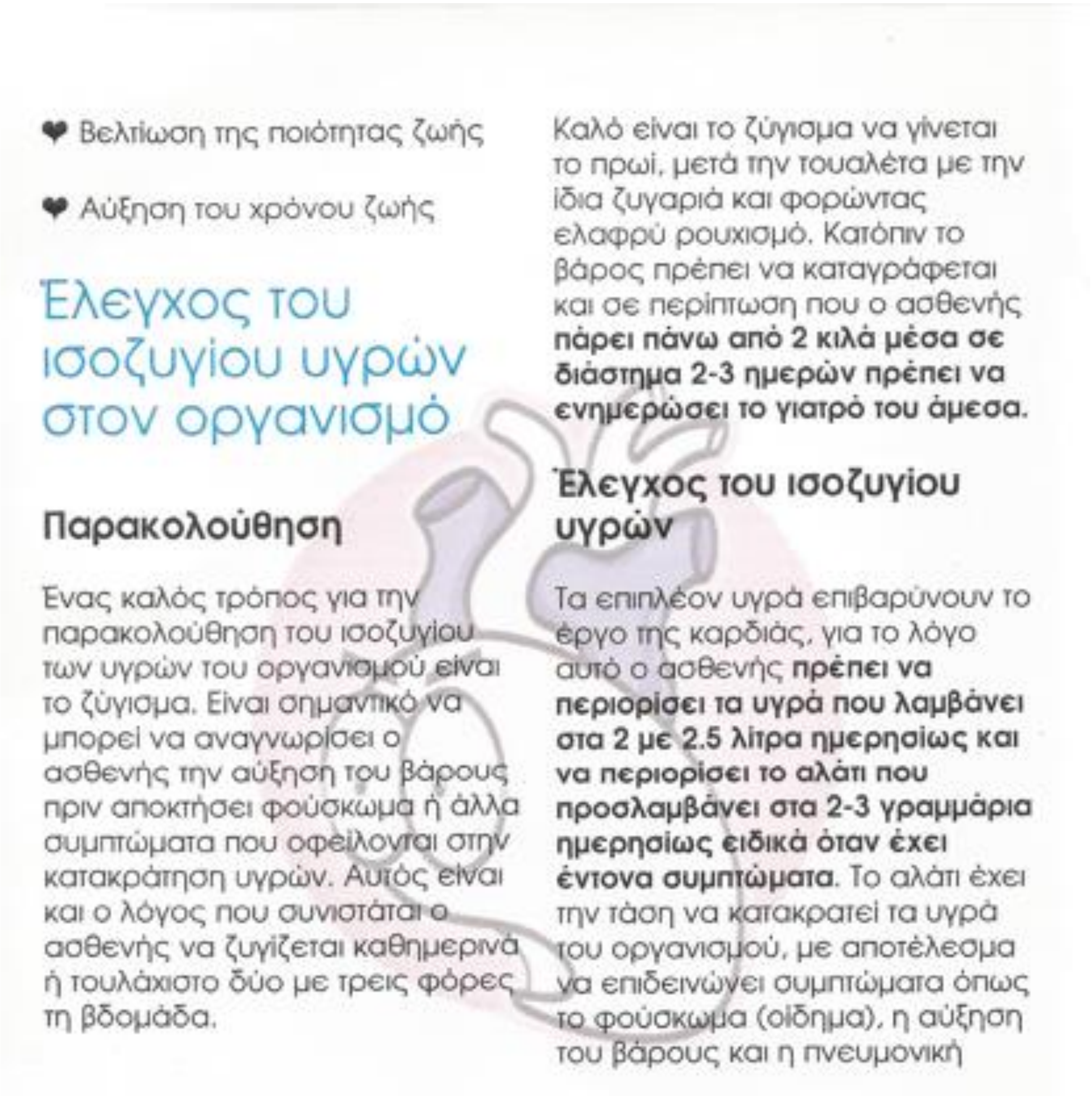
8 Έχεις φωτοφοβία ή πονοκέφαλο / ζάλη

9 Έχεις καλπάζοντα παλμό / Αίσθημα παλμών

Μη επεμβατική αντιμετώπιση της καρδιακής ανεπάρκειας

Στόχοι θεραπείας:

- ❤ Ανακούφιση του ασθενή από συμπτώματα, όπως είναι η δύσπνοια
- ❤ Ελάττωση του αισθήματος της κόπωσης/αδυναμίας
- ❤ Επιβράδυνση της εξέλιξης της νόσου
- ❤ Αύξηση της χρονικής περιόδου χωρίς επεισόδια που χρήζουν εισαγωγής στο νοσοκομείο



- Βελτίωση της ποιότητας ζωής
- Αύξηση του χρόνου ζωής

Έλεγχος του ισοζυγίου υγρών στον οργανισμό

Παρακολούθηση

Ένας καλός τρόπος για την παρακολούθηση του ισοζυγίου των υγρών του οργανισμού είναι το ζύγισμα. Είναι σημαντικό να μπορεί να αναγνωρίσει ο ασθενής την αύξηση του βάρους πριν αποκτήσει φούσκωμα ή άλλα συμπτώματα που οφείλονται στην κατακράτηση υγρών. Αυτός είναι και ο λόγος που συνιστάται ο ασθενής να ζυγίζεται καθημερινά ή τουλάχιστο δύο με τρεις φόρες τη βδομάδα.

Καλό είναι το ζύγισμα να γίνεται το πρωί, μετά την τουαλέτα με την ίδια ζυγαριά και φορώντας ελαφρύ ρουχισμό. Κατόπιν το βάρος πρέπει να καταγράφεται και σε περίπτωση που ο ασθενής **πάρει πάνω από 2 κιλά μέσα σε διάστημα 2-3 ημερών πρέπει να ενημερώσει το γιατρό του άμεσα.**

Έλεγχος του ισοζυγίου υγρών

Τα επιπλέον υγρά επιβαρύνουν το έργο της καρδιάς, για το λόγο αυτό ο ασθενής **πρέπει να περιορίσει τα υγρά που λαμβάνει στα 2 με 2.5 λίτρα ημερησίως και να περιορίσει το αλάτι που προσλαμβάνει στα 2-3 γραμμάρια ημερησίως ειδικά όταν έχει έντονα συμπτώματα**. Το αλάτι έχει την τάση να κατακρατεί τα υγρά του οργανισμού, με αποτέλεσμα να επιδεινώνει συμπτώματα όπως το φούσκωμα (οίδημα), η αύξηση του βάρους και η πνευμονική

συμφόρηση (δύσπνοια). Το αλάτι μπορεί να αναγράφεται ως "Νάτριο (Na+)" στα σκευάσματα των τροφών και πρέπει να είναι σε θέση ο ασθενής να υπολογίζει την ποσότητα που περιέχεται στις τροφές διαβάζοντας την ετικέτα.

Συμβουλές στους ασθενείς για περιορισμό στο αλάτι:

- Απομάκρυνε την αλατιέρα από το τραπέζι
- Μην προσθέτεις αλάτι στο φαγητό σου κατά το μαγείρεμα
- Επέλεξε τροφές στην "ανάλατη" τους έκδοση
- Μάθε πώς να διαβάζεις τις ετικέτες των τροφίμων
- Απόφευγε τις κονσερβοποιημένες τροφές και τα κατεψυγμένα τρόφιμα γιατί περιέχουν πολύ αλάτι
- Αντικατέστησε το αλάτι με διάφορα άλλα μπαχαρικά (σκόρδο, πιπέρι, κανέλα) και λεμόνι. Μαγείρεψε το φαγητό με κρεμμύδι πουπροσθέτει γεύση
- Ρώτησε το γιατρό σου πριν χρησιμοποιήσεις υποκατάστατα αλατιού γιατί μπορεί να είναι υψηλής περιεκτικότητας σε κάλιο και πιθανόν να αντενδείκνυνται λόγω της φαρμακευτικής σου αγωγής
- Μπορείς να καταγράφεις την ποσότητα του αλατιού που καταναλώνεις σε ημερήσιους πίνακες για να έχεις τον έλεγχο

αλλαγή τρόπου ζωής...

Ένας υγιεινός τρόπος ζωής μπορεί να διατηρήσει τον ασθενή με καρδιακή ανεπάρκεια σε μια καλή φυσική κατάσταση και να βελτιώσει γενικά την ποιότητα ζωής του αποφεύγοντας τις επιπλοκές. Πέραν του περιορισμού στα υγρά και στο αλάτι, ο ασθενής με καρδιακή ανεπάρκεια πρέπει να **αποφεύγει το κάπνισμα** και **να μην καταναλώνει μεγάλες ποσότητες οινόπνευμα (αλκοόλ)**. Πρέπει να ανοσοποιείται με εμβολιασμό κάθε χρόνο ενάντια στην γρίπη και τον πνευμονιόκοκκο, ενώ παράλληλα επιβάλλεται να παραμένει δραστήριος.

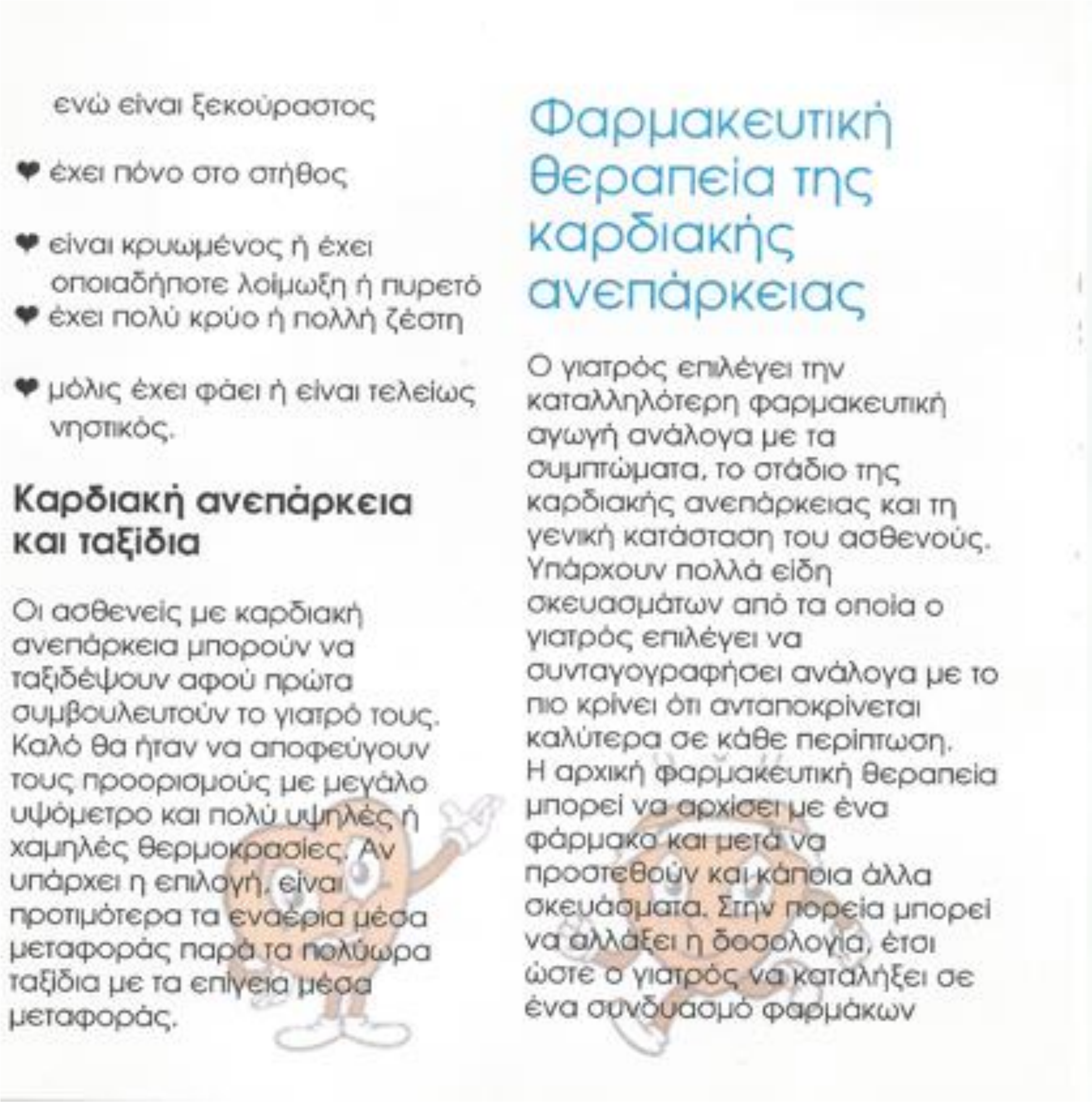
Καρδιακή ανεπάρκεια και άσκηση

Στα ενδιάμεσα διαστημάτων ξεκούρασης ο ασθενής συνιστάται να ακολουθεί ένα πρόγραμμα άσκησης το οποίο θα συζητήσει και θα σχεδιάσει με το γιατρό του (πχ ποδηλασία, περπάτημα, κολύμπι). Το να ασκείται συχνά θα τον βοηθήσει να διατηρήσει μια καλή φόρμα και να τονωθεί ψυχικά κάνοντάς τον να νιώθει ζωντάνια. Με το να παραμένει δραστήριος θα μπορεί να κάνει πιο πολλά πράγματα κατά τη διάρκεια της μέρας.

Υπάρχουν πολλές αεροβικές ασκήσεις από τις οποίες ο ασθενής μπορεί να επιλέξει να κάνει. Οι ισομετρικές ασκήσεις (αυτές που απαιτούν να κρατήσεις την αναπνοή) πρέπει να αποφεύγονται όσο είναι δυνατόν.

Ο ασθενής πρέπει να αποφεύγει την άσκηση σε περίπτωση που:

❤ έχει δυσκολία στην αναπνοή



ενώ είναι ξεκούραστος

- έχει πόνο στο στήθος
- είναι κρυωμένος ή έχει οποιαδήποτε λοίμωξη ή πυρετό
- έχει πολύ κρύο ή πολλή ζέστη
- μόλις έχει φάει ή είναι τελείως νηστικός.

Καρδιακή ανεπάρκεια και ταξίδια

Οι ασθενείς με καρδιακή ανεπάρκεια μπορούν να ταξιδέψουν αφού πρώτα συμβουλευτούν το γιατρό τους. Καλό θα ήταν να αποφεύγουν τους προορισμούς με μεγάλο υψόμετρο και πολύ υψηλές ή χαμηλές θερμοκρασίες. Αν υπάρχει η επιλογή, είναι προτιμότερα τα εναέρια μέσα μεταφοράς παρά τα πολύωρα ταξίδια με τα επίγεια μέσα μεταφοράς.

Φαρμακευτική θεραπεία της καρδιακής ανεπάρκειας

Ο γιατρός επιλέγει την καταλληλότερη φαρμακευτική αγωγή ανάλογα με τα συμπτώματα, το στάδιο της καρδιακής ανεπάρκειας και τη γενική κατάσταση του ασθενούς. Υπάρχουν πολλά είδη σκευασμάτων από τα οποία ο γιατρός επιλέγει να συνταγογραφήσει ανάλογα με το πιο κρίνει ότι ανταποκρίνεται καλύτερα σε κάθε περίπτωση. Η αρχική φαρμακευτική θεραπεία μπορεί να αρχίσει με ένα φάρμακο και μετά να προστεθούν και κάποια άλλα σκευάσματα. Στην πορεία μπορεί να αλλάξει η δοσολογία, έτσι ώστε ο γιατρός να καταλήξει σε ένα συνδυασμό φαρμάκων

ο οποίος να είνα αποτελεσματικός και ανεκτός από τον ασθενή.

Σημαντικές συμβουλές προς τους ασθενείς:

- Ακολούθησε πιστά τις οδηγίες που σου έχει δώσει ο γιατρός
- Φρόντισε να μάθεις να ονομάζεις τα φάρμακά σου, το λόγο που τα παίρνεις, τις δόσεις και τις παρενέργειές τους
- Μην παραλείπεις δόσεις φαρμάκων, σε περίπτωση που γίνει αυτό μην πάρεις διπλή δόση την επόμενη φορά
- Κάνε ένα σχεδιάγραμμα και αντιστοίχησε τις ώρες με τα φάρμακα που πρέπει να πάρεις κάθε φορά, αν δυσκολεύεσαι, ζήτησε βοήθεια από κάποιο ειδικό
- Θα ήταν σωστό να ελέγχεις την πίεσή σου καθημερινά, υπάρχουν φάρμακα ή συνδυασμός φαρμάκων που μπορεί να προκαλέσουν μεγάλες μεταβολές στην αρτηριακή πίεση
- Μπορείς να χρησιμοποιήσεις ένα ξυπνητήρι για να σε υπενθυμίζει να πάρεις τα φάρμακά σου
- Αν το βρίσκεις πρακτικό, μπορείς να χρησιμοποιήσεις κουτιά ειδικά για φάρμακα που έχουν χωρισμένα τα φάρμακα της βδομάδας ανάλογα με τις μέρες και τις ώρες που πρέπει να τα πάρεις
- Αν κάποιο από τα φάρμακα σου έχει προκαλέσει μια παρενέργεια, μην σταματήσεις να το παίρνεις αν δεν συμβουλευτείς πρώτα το γιατρό σου
- Αν παίρνεις δύο αγγειοδραστικά φάρμακα φρόντισε να τα

πάρεις με τουλάχιστο δύο ώρες διαφορά

❤ Μην πάρεις το διουρητικό χάπι αμέσως πριν πας για ύπνο, θα χρειαστεί να ξυπνήσεις κατά τη διάρκεια της νύχτας για να ουρήσεις.

Κατηγορίες Φαρμακευτικών Σκευασμάτων που Χρησιμοποιούνται στην Καρδιακή Ανεπάρκεια

❤ Αναστολείς μετατρεπτικού ενζύμου αγγειοτενσίνης (ΑΜΕΑ)

Πρόκειται για τα πρώτης γραμμής φάρμακα που χρησιμοποιούνται για τη διαχείριση της καρδιακής ανεπάρκειας. Μπλοκάρουν τη μετατροπή της αγγειοτενσίνης I σε αγγειοτενσίνη II. Η αναστολή του συστήματος από τους ΑΜΕΑ οδηγεί σε αγγειοδιαστολή, δηλαδή διεύρυνση των αγγείων. Αυτό έχει ως αποτέλεσμα τη βελτίωση της ροής του αίματος και μακροχρόνια την πτώση της αρτηριακής πίεσης. Η πιο συχνή παρενέργεια είναι ο ξηρός, επίμονος βήχας.

❤ Αναστολείς υποδοχέων αγγειοτενσίνης II

Πρόκειται για μια παραλλαγή των ΑΜΕΑ με παρόμοια δράση.

❤ Διουρητικά

Η δράση των διουρητικών έχει ως αποτέλεσμα τη μείωση του όγκου αίματος (υγρών) και νατρίου με τη διούρηση. Χαμηλώνουν την υψηλή πίεση διότι αποβάλλουν από το σώμα νερό και νάτριο που δεν χρειάζεται. Μειώνουν έτσι το φορτίο εργασίας της καρδιάς. Έτσι αποσυμφορίζονται οι πνεύμονες και ανακουφίζονται συμπτώματα, όπως είναι το φούσκωμα

(πρήξιμο) και η δύσπνοια. Η πιο κοινή ανεπιθύμητη ενέργεια είναι η απώλεια καλίου. Το κάλιο είναι σημαντικό συστατικό του οργανισμού και βοηθά στην ηλεκτρική σταθερότητα της καρδιάς και στην καλή λειτουργία του νευρικού συστήματος.

Οι ασθενείς πρέπει να παρακολουθούν τακτικά τις τιμές του καλίου στο αίμα. Πολλά φρούτα όπως οι μπανάνες, τα πορτοκάλια, τα γκρέιπφρουτ και τα λαχανικά περιέχουν κάλιο και η κατανάλωσή τους βοηθά αφού πρώτα το εγκρίνει και ο γιατρός.

❤ Βήτα αποκλειστές

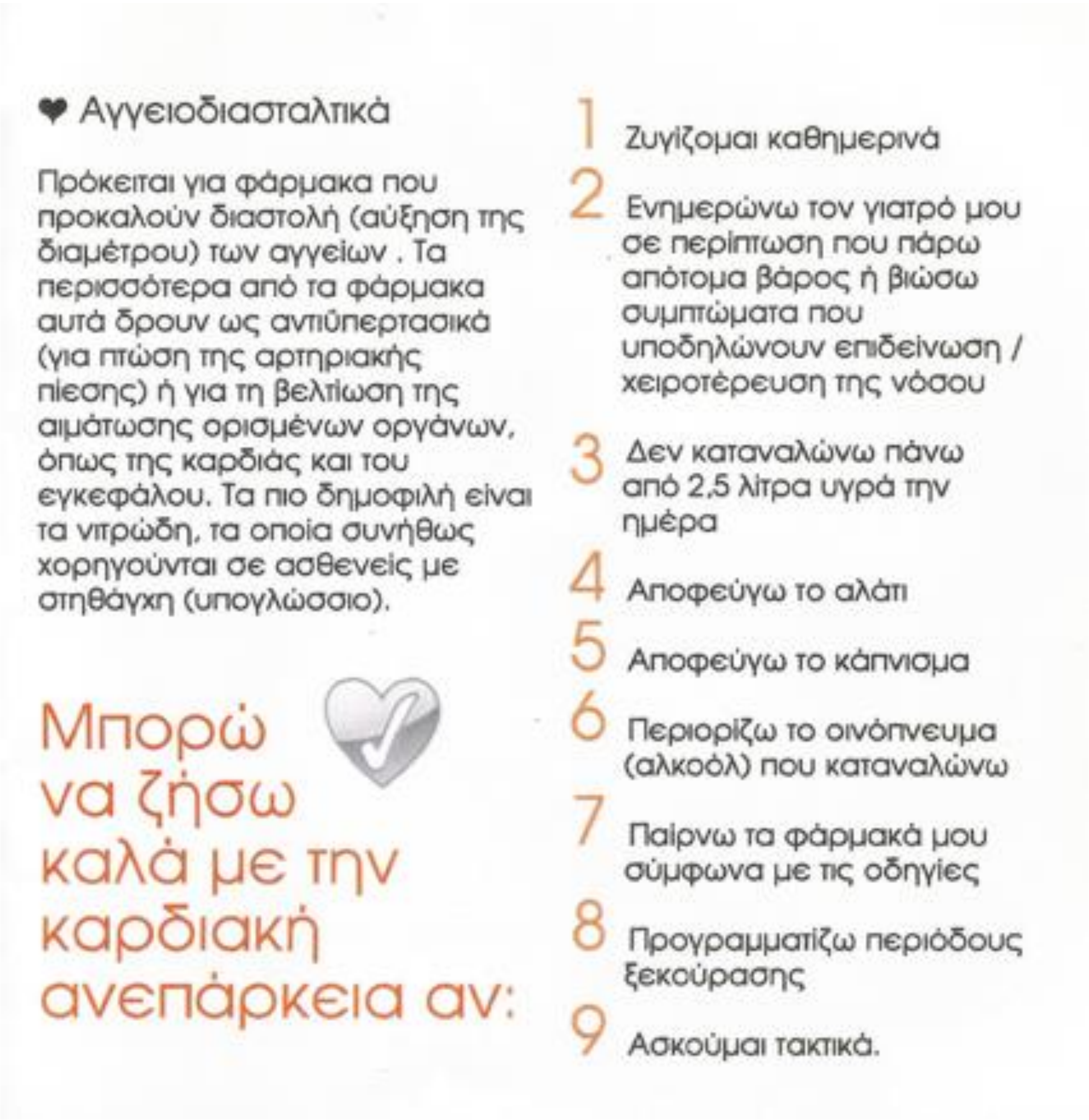
Περιορίζουν τη βλαπτική δράση της αδρεναλίνης στην καρδιά και στα αγγεία, ελέγχουν τον καρδιακό ρυθμό και μειώνουν την πίεση. Οι δράσεις τους είναι δύο: 1) Ελαττώνουν την καρδιακή συχνότητα (σφύξεις το λεπτό) με άμεσο αποτέλεσμα την ελάττωση των απαιτήσεων του μυοκαρδίου σε οξυγόνο και την ελάττωση του καρδιακού έργου και 2) Αυξάνουν το χρόνο αιμάτωσης των στεφανιαίων αρτηριών (αγγεία της καρδιάς).

❤ Διγοξίνη

Βελτιώνει τη συσταλτική λειτουργία της καρδιάς και δυναμώνει τον παλμό, επιτρέποντας στην καρδιά να προωθεί μεγαλύτερη ποσότητα αίματος. Τα επίπεδα της διγοξίνης πρέπει να ελέγχονται τακτικά με λήψη δείγματος αίματος για να αποφευχθεί η τοξικότητα από το φάρμακο.

❤ Σπιρονολακτόνη

Μπλοκάρει κάποιες ανεπιθύμητες δράσεις της αλδοστερόνης στην καρδιά και αποφορτίζει το σώμα από τα επιπλέον υγρά μέσω της διούρησης. Είναι δυνατόν να αυξήσει τα επίπεδα του καλίου στον οργανισμό.



❤ Αγγειοδιασταλτικά

Πρόκειται για φάρμακα που προκαλούν διαστολή (αύξηση της διαμέτρου) των αγγείων . Τα περισσότερα από τα φάρμακα αυτά δρουν ως αντιϋπερτασικά (για πτώση της αρτηριακής πίεσης) ή για τη βελτίωση της αιμάτωσης ορισμένων οργάνων, όπως της καρδιάς και του εγκεφάλου. Τα πιο δημοφιλή είναι τα νιτρώδη, τα οποία συνήθως χορηγούνται σε ασθενείς με στηθάγχη (υπογλώσσιο).

Μπορώ να ζήσω καλά με την καρδιακή ανεπάρκεια αν:

1 Ζυγίζομαι καθημερινά

2 Ενημερώνω τον γιατρό μου σε περίπτωση που πάρω απότομα βάρος ή βιώσω συμπτώματα που υποδηλώνουν επιδείνωση / χειροτέρευση της νόσου

3 Δεν καταναλώνω πάνω από 2,5 λίτρα υγρά την ημέρα

4 Αποφεύγω το αλάτι

5 Αποφεύγω το κάπνισμα

6 Περιορίζω το οινόπνευμα (αλκοόλ) που καταναλώνω

7 Παίρνω τα φάρμακά μου σύμφωνα με τις οδηγίες

8 Προγραμματίζω περιόδους ξεκούρασης

9 Ασκούμαι τακτικά.

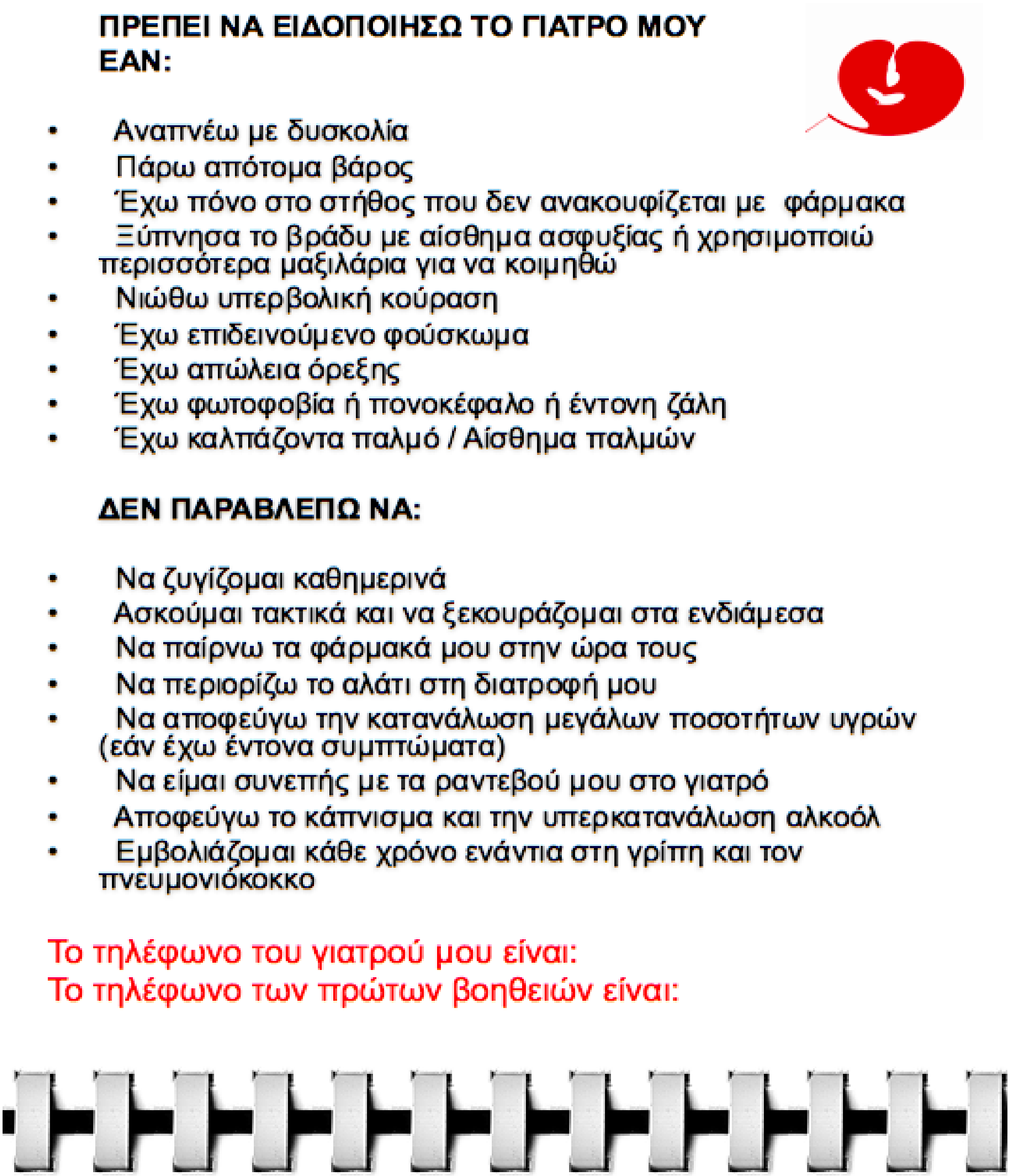
APPENDIX IX

A recording form with columns to daily record the weight, blood pressure, pulse and glucose level.

|		ΔΕΥΤΕΡΑ	ΤΡΙΤΗ	ΤΕΤΑΡΤΗ	ΠΕΜΠΤΗ	ΠΑΡΑΣΚ.	ΣΑΒΒΑΤΟ	ΚΥΡΙΑΚΗ
ΕΒΔ 1	**ΒΑΡΟΣ** (Kg)							
	ΠΙΕΣΗ **ΓΛΥΚΟΖΗ**							
	ΠΑΛΜΟΙ (ΧΤΥΠΟΙ ΤΟ ΛΕΠΤΟ)							
ΕΒΔ 2	**ΒΑΡΟΣ** (Kg)							
	ΠΙΕΣΗ **ΓΛΥΚΟΖΗ**							
	ΠΑΛΜΟΙ (ΧΤΥΠΟΙ ΤΟ ΛΕΠΤΟ)							
ΕΒΔ 3	**ΒΑΡΟΣ** (Kg)							
	ΠΙΕΣΗ **ΓΛΥΚΟΖΗ**							
	ΠΑΛΜΟΙ (ΧΤΥΠΟΙ ΤΟ ΛΕΠΤΟ)							
	ΒΑΡΟΣ (Kg)							
	ΠΙΕΣΗ							

	ΓΛΥΚΟΖΗ							
	ΠΑΛΜΟΙ (ΧΤΥΠΟΙ ΤΟ ΛΕΠΤΟ)							
ΕΒΔΑ 4	**ΒΑΡΟΣ** (Kg)							
	ΠΙΕΣΗ **ΓΛΥΚΟΖΗ**							
	ΠΑΛΜΟΙ (ΧΤΥΠΟΙ ΤΟ ΛΕΠΤΟ)							

APPENDIX X



ΠΡΕΠΕΙ ΝΑ ΕΙΔΟΠΟΙΗΣΩ ΤΟ ΓΙΑΤΡΟ ΜΟΥ ΕΑΝ:

- Αναπνέω με δυσκολία
- Πάρω απότομα βάρος
- Έχω πόνο στο στήθος που δεν ανακουφίζεται με φάρμακα
- Ξύπνησα το βράδυ με αίσθημα ασφυξίας ή χρησιμοποιώ περισσότερα μαξιλάρια για να κοιμηθώ
- Νιώθω υπερβολική κούραση
- Έχω επιδεινούμενο φούσκωμα
- Έχω απώλεια όρεξης
- Έχω φωτοφοβία ή πονοκέφαλο ή έντονη ζάλη
- Έχω καλπάζοντα παλμό / Αίσθημα παλμών

ΔΕΝ ΠΑΡΑΒΛΕΠΩ ΝΑ:

- Να ζυγίζομαι καθημερινά
- Ασκούμαι τακτικά και να ξεκουράζομαι στα ενδιάμεσα
- Να παίρνω τα φάρμακά μου στην ώρα τους
- Να περιορίζω το αλάτι στη διατροφή μου
- Να αποφεύγω την κατανάλωση μεγάλων ποσοτήτων υγρών (εάν έχω έντονα συμπτώματα)
- Να είμαι συνεπής με τα ραντεβού μου στο γιατρό
- Αποφεύγω το κάπνισμα και την υπερκατανάλωση αλκοόλ
- Εμβολιάζομαι κάθε χρόνο ενάντια στη γρίπη και τον πνευμονιόκοκκο

Το τηλέφωνο του γιατρού μου είναι:
Το τηλέφωνο των πρώτων βοηθειών είναι:

APPENDIX XI

A fridge magnet with the logo of the ‘SupportHeart’

APPENDIX XII

Non - pharmacological education for the intervention group.

Fluid and sodium management

Although in the guidelines for HF recommend restriction to fluid and sodium intake, there is no any scientific documentation and in the latest ESC quidelines, this recommendation stated as to avoid excessive fluid intake (Ponikowski et al. 2016, McDonagh et al. 2021). The patients were educated about fluid restriction and they recommended to take no more than 1.5–2 liters/day to avoid signs of congestion like, dyspnea or difficult sleeping without pillows,weight gain more than 2kg in 3-4 days or ankle swelling (Parinello et al., 2015) .They educated and learned that the presence of signs/symptoms related to elevated fluids is due to the elevated intracardiac filling pressures and that is very iimportant the early recognition of these signs/symptoms by themselves or their caregivers.This is very important in order to prevent the deterioration of the symptoms and acute events that will decreasd their HR-QoL. These pressures may begin to increase days until three weeks prior to the development of symptoms or weight gain (Parinello et al., 2015). A recording form was given to the patients in the meetings that included columns to record every day their weight, blood pressure, heart beats and glucose level so they can assess with the research team the measurements and manage their condition and over time to manage it themselves (Appendix 21). They were given a fridge magnet with the logo of ‘SupportHeart’ to attach the form, so that it reminded them to record the measurements daily (Appendix 23). During the summer days or during the hot days, especially in Cyprus where the temperature during summer rises to 39-44 degrees Celsius, patients learned to lick an ice cube rather than take extra fluids so they will feel that they have quenched their thirst but without overload their body with extra fluids. During the study, a patient diagnosed with DM2.

Although guidelines for HF recommend restriction to sodium intake, there is no any large RCT designed yet with the aim to determine the effect of low sodium intake on clinical outcomes, including cardiovascular events and mortality (O'Donnell et al. 2020, McDonagh et al. 2021). However, the presence of higher sodium intake in DM patients with HF seems to increase the risk of fluid retention, hypervolemia, and acute decompensated HF (Rosano et al. 2017). This can be explained by glucose having similar osmotic characteristics as sodium, displacing fluids from intracellular and extravascular spaces into intravascular space causing hypervolemia (Rosano et al., 2017) European Guidelines indicate restriction of sodium intake to ‹ 2.000 mg/day in symptomatic patients (McDonagh et al. 2021). The Heart Failure Society of America recommends 2.000–3.000 mg daily sodium intake for patients with HF and preserved or depressed EF, with further restriction ‹ 2.000 mg/day for moderate to severe HF and patients with volume overload (Alderman & Cohen., 2012). Patients learned to folow a low dodium diet, read carefully the labels in food for the presence of sodium chloride (NaCl) and avoid pre-cooked foods that contain a high amount of salt and replace salt with spices and herbs.

Fat and sugar free diet

Current mechanisms underlying the beneficial effects of the Mediterranean diet that include a depletion in inflammatory and oxidative stress markers, improvement in lipid profile, insulin sensitivity and endothelial function, and has antithrombotic properties (Ditano-Vázquez et al., 2019). Most of these effects are due to bioactive ingredients including polyphenols, mono- and poly-unsaturated fatty acids that contains to olive oil (Ditano-Vázquez et al., 2019). In RCTs, the Mediterranean diet found to decrease fasting plasma glucose, systolic and diastolic blood pressure, body weight, waist circumference, low density lipoprotein (LDL) cholesterol and triglycerides (Kahleova et al., 2019). According to the Diabetes and Nutrition Study Group (DNSG) of the European Association for the Study of Diabetes (EASD) 2023, support that mediterranean diet is characterised by high consumption of vegetables, legumes, whole grains, fruits, nuts and extra virgin olive oil. It also recommends, moderate consumption of fish and wine, and low consumption of red and processed meat, processed food and Mediterranean diet is recommended in patients with HF- DM (Reynolds et al. 2023). Patients learned about the benefits to follow the Mediterranean diet but without the intake of products that contain sugar and limited portion of fruits. The 'SupportHeart' research team gave additional nutritional advice related to special occasions like religious fasting periods to meet the spiritual needs of the patients but without causing any fluid overloading or episodes of hyperglycaemia taking into consideration and other comorbidities like impaired renal disease.

Physical activity

HF is characterized by intolerance to exercise, and HF patients get tired easily and experience shortness of breath. Previous years was adviced HF patients to avoid physical activity. However, the new management of HF impose physical activity in the management of HF and DM, with multiple benefits for the patients (Sato et al., 2012). RCTs have found that physical activity improves HbA1c, triglycerides and cholesterol in people with DM2 (Balducci et al. 2012, Liubaoerjijin et al.,2016).

In DM1, aerobic exercise increases cardiorespiratory fitness, decreases insulin resistance, and improves endothelial function and lipids (Chimen et al, 2012). Moderate to high levels of physical activity and cardiorespiratory fitness are associated with substantially lower morbidity and mortality in people with DM1 and DM2 (Sigal et al. 2018). It is recommended that HF patients can exercise for 20–60 minutes, 3–5 days per week at moderate-to-high intensity. The deconditioned patients can start low intensity physical activity 5-10 minutes, twice a week and gradually can reach the above recommendation (Piepoli et al., 2021). Aerobic ecercise recommended most because it increases insulin sensitivity, oxidative enzymes, increases lung function, increases immune function, and cardiac output (Garber et al., 2012). Prior exercising glucose level has to be checked and patients in the IG learned about the benefits of physical activity and the possibility to have hypoglycaemia during or after exercising. During the monthly meetings with the patients several times was arranged walking according to the endurance of each patient. Prior exercise HF-DM patients must check their glucose level especially patients who receive insulin to prevent episodes of hypoglycaemia during the exercise.

Smoking

Smoking increases blood pressure, pulmonary artery pressure and vascular resistance and is associated with carbon monoxide exposure, increasing oxidative stress which lead to impaired mitochondrial function, inflammation and impaired endothelial function (Kamimura et al., 2018) In addition smoking causes directly damage of β-cell function and the chemical compounds of tampacco leads to smoke-related insulin resistance (Wannamethee et al., 2001). Inflammation and impaired endothelial function may influence the myocardium by affecting cardiac structure and function or indirectly causing arterial atherosclerosis (Bye et al., 2008). Patients learned about the clinical benefits for smoking cessation and the smokers advised to quit smoking since smoking cessation prevents hospitalization and death (Suskin et al., 2001).

Travel

Patients with HF and DM must consult their doctors before travelling. They must take with them their medications with a brief letter from their doctor describing their medical problem (Possick. 2007, Izabi et al. 2014). Furthermore, patients with cardiac pacemaker or implantable cardioverter defibrillator assured that they could fly with safety (Izabi et al., 2014). They were advised to have their device card ready to show to airport personnel before walking through the security checkpoint. The pressure of the cabin and the anxiety that a person can experience during air flight can decrreased oxygen saturation (Izabi et al., 2014). Stable patients with NYHA class I–III are able to travel with safety (Smith et al., 2010). However, patients with NYHA class III were advised to have on flight, medical oxygen support. Patients with NYHA class IV should not travel without oxygen and medical assistance.

APPENDIX XIII

ΕΡΩΤΗΜΑΤΟΛΟΓΙΟ: 'ΖΩΝΤΑΣ ΜΕ ΤΗΝ ΚΑΡΔΙΑΚΗ ΑΝΕΠΑΡΚΕΙΑ'

Οδηγίες χρήσης

1. Οι ασθενείς πρέπει να απαντήσουν το ερωτηματολόγιο πριν από άλλες αξιολογήσεις και επαφές που μπορεί να προκαταλάβουν τις απαντήσεις. Μπορείτε να πείτε στον ασθενή ότι θα θέλατε να πάρετε τη γνώμη του πριν να κάνει άλλες ιατρικές εξετάσεις.

2. Άφθονος, χωρίς διακοπή χρόνος πρέπει να διατεθεί ώστε ο ασθενής να συμπληρώσει το ερωτηματολόγιο.

3. Οι οδηγίες που ακολουθούν πρέπει να δίνονται στον ασθενή κάθε φορά που το ερωτηματολόγιο συμπληρώνεται.

    α. Διαβάστε στον ασθενή την εισαγωγική παράγραφο που βρίσκεται στην κορυφή του ερωτηματολογίου.

    β. Διαβάστε την πρώτη ερώτηση στον ασθενή - "Σας εμπόδισε η καρδιακή σας ανεπάρκεια από το να ζείτε όπως θέλατε κατά τον περασμένο μήνα προκαλώντας πρήξιμο στους αστραγάλους σας ή στα πόδια"; Πείτε στον ασθενή, "Αν δεν είχατε καθόλου πρήξιμο στους αστραγάλους ή στα πόδια κατά τον περασμένο μήνα πρέπει να βάλετε σε κύκλο το μηδέν μετά από αυτήν την ερώτηση για να δείξετε ότι το πρήξιμο δεν ήταν πρόβλημα κατά τον περασμένο μήνα". Εξηγήστε στον ασθενή ότι αν είχε πρήξιμο που προκλήθηκε από στραμπούλημα του αστράγαλου ή από κάποια άλλη αιτία η οποία σίγουρα δεν σχετιζόταν με την καρδιακή ανεπάρκεια πρέπει επίσης να βάλει σε κύκλο το μηδέν. Πείτε στον ασθενή, "Αν δεν είσαστε σίγουρος για ποιο λόγο είχατε το πρήξιμο ή νομίζετε ότι αυτό σχετιζόταν με το πρόβλημα της καρδιάς σας, τότε βαθμολογήστε πόσο πολύ το πρήξιμο σας εμπόδισε από το να κάνετε πράγματα που θέλατε να κάνετε και από το να νιώθετε όπως θα θέλατε να νιώθετε". Με άλλα λόγια, πόσο ενοχλητικό ήταν το πρήξιμο; Δείξτε στον ασθενή πώς να χρησιμοποιεί την κλίμακα από το 1 μέχρι το 5 για να σημειώνει πόσο πολύ το πρήξιμο επηρέασε τη ζωή του κατά τον περασμένο μήνα - από πολύ λίγο μέχρι πάρα πολύ.

4. Αφήστε τον ασθενή να διαβάσει και να απαντήσει τις άλλες ερωτήσεις. Ολόκληρο το ερωτηματολόγιο μπορεί να διαβαστεί απευθείας στον ασθενή, αν κάποιος προσέξει να μην επηρεάσει τις απαντήσεις με λεκτικά ή σωματικά μηνύματα.

5. Επιβεβαιώστε ότι ο ασθενής έχει απαντήσει σε όλες τις ερωτήσεις και ότι υπάρχει μια μόνον απάντηση σε κάθε ερώτηση σημειωμένη καθαρά. Αν κάποιος ασθενής διαλέξει να μην απαντήσει κάποια/ες ερωτήσεις σημειώστε το στο ερωτηματολόγιο.

6. Βαθμολογήστε το ερωτηματολόγιο προσθέτοντας τις απαντήσεις και των 21 ερωτήσεων. Επιπλέον, σωματικές (ερωτήσεις 2, 3, 4, 5, 6, 7, 12 και 13) και συναισθηματικές (ερωτήσεις 17, 18, 19, 20, και 21) διαστάσεις του ερωτηματολογίου έχουν βρεθεί με ανάλυση παραγόντων, και μπορούν να εξεταστούν ώστε να χαρακτηρίσουν παραπέρα την επίδραση της καρδιακής ανεπάρκειας στη ζωή κάποιου ασθενούς.

ΕΡΩΤΗΜΑΤΟΛΟΓΙΟ: 'ΖΩΝΤΑΣ ΜΕ ΤΗΝ ΚΑΡΔΙΑΚΗ ΑΝΕΠΑΡΚΕΙΑ'

Αυτές οι ερωτήσεις αφορούν τον τρόπο με τον οποίο η καρδιακή σας ανεπάρκεια (πρόβλημα της καρδιάς) σας εμπόδισε από το να ζείτε όπως θέλατε κατά τον περασμένο μήνα. Οι ερωτήσεις της παρακάτω λίστας περιγράφουν διαφορετικούς τρόπους με τους οποίους μερικοί άνθρωποι επηρεάζονται. Αν είστε σίγουρος ότι μια ερώτηση δεν σας αφορά ή δεν σχετίζεται με την καρδιακή σας ανεπάρκεια βάλτε σε κύκλο το 0 (Όχι) και πηγαίνετε στην επόμενη ερώτηση. Αν μια ερώτηση σας αφορά, τότε βάλτε σε κύκλο τον αριθμό που αξιολογεί το πόσο πολύ σας εμπόδισε από το να ζείτε όπως θέλατε.

Σας εμπόδισε η καρδιακή σας ανεπάρκεια από το να ζείτε όπως θέλατε κατά τον περασμένο μήνα:

	Όχι	Πολύ λίγο				Πάρα πολύ
1. Προκαλώντας πρήξιμο στους αστραγάλους σας, τα πόδια, κ.λ.π.;	0	1	2	3	4	5
2. Κάνοντάς σας να καθόσαστε ή να ξαπλώνετε για να ξεκουράζεστε κατά τη διάρκεια της ημέρας;	0	1	2	3	4	5
3. Δυσκολεύοντας το περπάτημά σας ή το ανέβασμα σκάλας;	0	1	2	3	4	5
4. Δυσκολεύοντας τις δουλειές σας στο σπίτι ή στην αυλή;	0	1	2	3	4	5
5. Δυσκολεύοντας το να βγαίνετε έξω μακριά από το σπίτι;	0	1	2	3	4	5
6. Δυσκολεύοντάς σας από το να κοιμάστε καλά τη νύχτα;	0	1	2	3	4	5
7. Δυσκολεύοντας τις σχέσεις σας ή το να κάνετε πράγματα με τους φίλους σας ή την οικογένεια;	0	1	2	3	4	5

8.	Δυσκολεύοντας την εργασία σας που σας αποφέρει εισόδημα;	0	1	2	3	4	5
9.	Δυσκολεύοντας την ψυχαγωγία σας, τα σπορ ή τα χόμπυ σας;	0	1	2	3	4	5
10.	Δυσκολεύοντας τις σεξουαλικές σας δραστηριότητες;	0	1	2	3	4	5
11.	Κάνοντάς σας να τρώτε λιγότερο από τα φαγητά που σας αρέσουν;	0	1	2	3	4	5
12.	Κάνοντάς σας να λαχανιάζετε;	0	1	2	3	4	5
13.	Κάνοντάς σας να νιώθετε κουρασμένος, αδύναμος ή με χαμηλή ενεργητικότητα;	0	1	2	3	4	5
14.	Κάνοντάς σας να παραμένετε σε νοσοκομείο;	0	1	2	3	4	5
15.	Κοστίζοντάς σας χρήματα για ιατρική φροντίδα;	0	1	2	3	4	5
16.	Προκαλώντας σας παρενέργειες από τα φάρμακα;	0	1	2	3	4	5
17.	Κάνοντάς σας να νιώθετε ότι είσαστε βάρος στην οικογένειά σας ή τους φίλους;	0	1	2	3	4	5
18.	Κάνοντάς σας να νιώθετε ότι χάσατε τον έλεγχο του εαυτού σας στη ζωή σας;	0	1	2	3	4	5
19.	Κάνοντάς σας να ανησυχείτε;	0	1	2	3	4	5
20.	Δυσκολεύοντας το να συγκεντρώνεστε ή να θυμάστε πράγματα;	0	1	2	3	4	5
21.	Κάνοντάς σας να νιώθετε κατάθλιψη;	0	1	2	3	4	5

APPENDIX XIV

Δείκτης αυτοφροντίδας στην Καρδιακή Ανεπάρκεια

Όλες οι απαντήσεις είναι εμπιστευτικές

Καθώς θα απαντάς τις παρακάτω ερωτήσεις να σκέφτεσαι πως αισθάνεσαι τον τελευταίο μήνα ή από την τελευταία μερα επικοινωνίας μαζί μας μέχρι σήμερα.

ΜΕΡΟΣ Α:

Στη παρακάτω λίστα υπάρχουν οδηγίες που δίνονται σε άτομα με Καρδιακή Ανεπάρκεια. Πώς εφαρμόζονται τα παρακάτω ως ρουτίνα;

	Ποτέ ή Σπάνια	**Μερικές Φορές**	**Συχνά**	**Πάντα ή Καθημερινά**
1. Ζυγίζεσαι;	1	2	3	4
2. Ελέγχεις τους αστραγάλους σου για πρήξιμο;	1	2	3	4
3. Προφυλάσσεις τον εαυτό σου από το να αρρωστήσει; (π.χ. εμβόλιο γρίπης, αποφυγή άρρωστων ατόμων)	1	2	3	4
4. Κάνεις φυσική δραστηριότητα;	1	2	3	4
5. Τηρείς τα ραντεβού με το γιατρό ή το νοσηλευτή σου;	1	2	3	4
6. Ακολουθείς διατροφή χαμηλή σε αλάτι;	1	2	3	4
7. Κάνεις άσκηση για 30 λεπτά;	1	2	3	4
8. Ξεχνάς να πάρεις κάποιο από τα φάρμακα σου;	1	2	3	4
9. Ζητάς για τρόφιμα χαμηλά σε αλάτι, όταν τρως έξω ή σε επίσκεψη;	1	2	3	4

10. Χρησιμοποιείς κάποια μέθοδο (κουτί χαπιών, υπενθυμίσεις) για να σε βοηθά να θυμάσαι τα φάρμακα σου;	1	2	3	4

ΜΕΡΟΣ Β:

Πολλοί ασθενείς έχουν συμπτώματα λόγω της καρδιακής τους ανεπάρκειας. Συνηθισμένα συμπτώματα της καρδιακής ανεπάρκειας είναι η δυσκολία στην αναπνοή και το πρήξιμο των αστραγάλων.

Τον τελευταίο μήνα , έχεις δυσκολία στην αναπνοή ή πρήξιμο στους αστραγάλους; Κύκλωσε ένα.

0) Όχι
1) Ναι

Εάν είχες δυσκολία στην αναπνοή ή πρήξιμο στους αστραγάλους τον τελευταίο μήνα…..

(Κυκλώστε **ένα** αριθμό)

	Δεν είχα αυτά τα συμπτώματα	**Δεν το αναγνώρισα**	**Όχι γρήγορα**	**Σχετικά γρήγορα**	**Γρήγορα**	**Πολύ γρήγορα**
Πόσο γρήγορα το αναγνώρισες ως σύμπτωμα καρδιακής ανεπάρκειας?	Δ/Α	0	1	2	3	4

Στη πιο κάτω λίστα αναφέρονται τρόποι αντιμετώπισης που χρησιμοποιούν άτομα με καρδιακή ανεπάρκεια. Εάν έχεις δυσκολία στην αναπνοή ή πρήξιμο στους αστραγάλους, πόσο είναι πιθανό να δοκιμάσεις κάποιο από τους παρακάτω τρόπους;

(Κυκλώστε **ένα** αριθμό για κάθε τρόπο αντιμετώπισης)

	Καθόλου Πιθανό	**Κάπως Πιθανό**	**Πιθανό**	**Πολύ Πιθανό**
11. Μειώνεις το αλάτι στη διατροφή	1	2	3	4
12. Μειώνεις την πρόσληψη υγρών	1	2	3	4
13. Παίρνεις έξτρα διουρητικό χάπι	1	2	3	4
14. Τηλεφωνείς στο γιατρό ή το νοσηλευτή για οδηγίες	1	2	3	4

15) Σκέψου ένα τρόπο αντιμετώπισης που δοκίμασες την τελευταία φορά που είχες δυσκολία στην αναπνοή ή πρήξιμο στους αστραγάλους,

(Κύκλωσε **ένα** αριθμό)

	Δεν δοκίμασα κάτι	**Δεν είμαι σίγουρος/η**	**Σχετικά σίγουρος/η**	**Σίγουρος/η**	**Πολύ σίγουρος/η**
Πόσο σίγουρος/η είσαι ότι ο τρόπος αντιμετώπισης βοήθησε ή όχι;	0	1	2	3	4

ΜΕΡΟΣ Γ:

Γενικά, πόση αυτοπεποίθηση έχεις ότι μπορείς να:

	Δεν έχω αυτοπεποίθηση	**Λίγη αυτοπεποίθηση**	**Πολύ αυτοπεποίθηση**	**Εξαιρετική αυτοπεποίθηση**
15. Διατηρείς τον εαυτό σου <u>χωρίς συμπτώματα καρδιακής ανεπάρκειας;</u>	1	2	3	4

16. Ακολουθείς θεραπευτικές οδηγίες που σου έχουν δοθεί;	1	2	3	4
17. Αξιολογείς τη σοβαρότητα των συμπτωμάτων σου;	1	2	3	4
18. Αναγνωρίσεις τις αλλαγές στην υγείας σου όταν αυτές συμβαίνουν;	1	2	3	4
19. Κάνεις κάτι που θα ανακουφίσει τα συμπτώματα σου;	1	2	3	4
20. Εκτιμάς πόσο καλά λειτουργεί ένας τρόπος αντιμετώπισης;	1	2	3	4

APPENDIX XV

The translation and validation of the Greek version of the SCHFI questionaire.

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RESEARCH ARTICLE

Development and Validation of the Greek version of Self-Care Heart Failure Index (Gr-SCHFI) in Patients with Heart Failure

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ABSTRACT
Background: Self-care of patients with heart failure (HF) is essential for the effective self-management of their disease, especially during the pandemic era. Self-care assessment instruments give the opportunity to Health Professionals to early recognize possible self-care needs and management of patients with HF.
Aim: The translation and validation of the Greek version of the instrument "Self-Care of Heart Failure Index" (Gr-SCHFI), as well as the investigation of the psychometric properties of the instrument in a Greek-speaking population with HF.
Methods: It's a methodological study of an instrument validation. The psychometric properties of the Greek version of Gr-SCHFI were evaluated through reliability factors (Cronbach's a and Composite Reliability), reliability of repeat test-retest and validity measures (content validity and concurrent validity). Brislin's (1970) methodology was used to translate the instrument to Greek language.
Results: The study involved 176 patients, of whom 138 (78%) were men with an average of 69 years old. Most participants were in the NYHA III category [76 (57%)]. Confirmatory factor analysis showed very good measurements in the criteria: RMSEA = 0.07, CFI = 0.97, GFI = 0.98, AGFI = 0.98, NFI = 0.95, TLI = 0.97. The Cronbach's alpha index and the Composite reliability index had satisfactory internal coherence indicators (Cronbach's alpha 0.80-0.92, and Composite reliability 0.88-0.96, respectively).
Conclusions: The Gr-SCHFI scale is a reliable and valid self-care assessment instrument for patients with HF. Self-care is necessary in HF where the evaluation and assessment of the self-care of the specific population is very important along the trajectory of the disease.

Keywords: Heart failure, Self-care, Self-management, Psychometric properties, Self-Care of Heart Failure Index

INTODUCTION

Heart Failure (HF) is a complex clinical syndrome related with many comorbidities, which complicate the long-term management of the disease, one of the major problems of public health[1]. In order to remain healthy, patients with HF must adhere to several behaviors and actions such as medication adherence, following a low-salt diet and staying physically active making this process difficult) [2].

Self-care is defined as a naturalistic decision-making process that involves the choice of behaviors which maintain the physiologic stability (self-care maintenance) and the response to symptoms when these symptoms occur (self-care management) [3–4]. It is fundamental for the clinical outcomes of patients with HF like in all chronic illnesses[5].

Self-care is substantial for the effective management of HF resulting to a better health related quality of life (QOL), lowering readmission rates, and reducing mortality[6]. To evaluate the adherence to self-care recommendations valid and reliable measures of self -care are needed. The evaluation of the self-care of patients with HF require the use of valid and reliable instruments. The most widely used scales are the European Heart Failure Self-care Behaviour Scale (EHFScBS)[7] and the Self-care Heart Failure Index (SCHFI)[3].

During the COVID-19 pandemic, the self-care management for these patients has become more essential, since patients with HF stay at home with minimum contacts and/or to their health professionals/clinics even though close monitoring is critical[5,8]. Therapeutic inertia in HF care is an ongoing risk and during this period communication and monitoring are impaired and patients with HF or other cardiovascular diseases are at risk for severe infection and complications[8,10]. The instruments assessing self-care management are now more than ever helpful to identify gaps in self-management, place of improvement and educational needs or lack of knowledge. Alternative therapeutic pathways and forms of monitoring are developed during the pandemic to ensure the continued provision of evaluation and good healthcare and prevention strategies, and the prompt management of deterioration while social distancing[11].

The validation of the SCHFI was decided to be established as is a comprehensive instrument giving the possibility to researchers and cardiology specialists of an alternative instrument, since Gr9-EHFScBS[12] has already been evaluated and used among Greek speaking populations. The SCHFI gives further the possibility to assess confidence as well[12]. The purpose of this study was to evaluate the psychometric properties of the Greek version of "Self-Care of Heart Failure Index" (Gr-SCHFI) questionnaire in Greek-speaking population.

METHODS

Study Design

It's a methodological study assessing measures of construct and discriminant validity, as well as the internal consistency and factor determinacy of the Gr-SCHFI and its factors.

Setting and sample

The sample consisted of 176 Greek speaking diagnosed patients with HF (NYHA class I-IV), that were recruited from cardiology units and outpatient departments of all large public hospitals of Cyprus, and outpatients of the Heart Failure Clinic from a large University Hospital in Athens, Greece. The participants completed a questionnaire which included questions on demographic and clinical characteristics, the Greek version of Self-Care management of Heart Failure Index (Gr-SCHFI) and the Greek version of the European Heart Failure Self-Care Behaviour Scale (Gr9-EHFScBS)[12].

Nurse researchers screened the patients during their hospitalization or scheduled visit in the HF clinic for possible participation. Only patients who were able to give written consent were included in the study. Patients who did not speak Greek, those with impaired cognitive function or with other conditions that severely affected their QoL (e.g. degenerative diseases, mental disorders, active cancer, on dialyses) were excluded. The questionnaire was administered by the nurse researcher who supervised the completion procedure. Participants with literacy problems or experiencing difficulty completing the questionnaire were interviewed by the nurse researcher.

Instruments

Self-Care of Heart Failure Index

The SCHFI (version 6.2) includes three sub-scales (dimensions) with 22 items measuring self-care maintenance (10 items), self-care management (6 items) and self-care confidence scale which includes six items. Each SCHFI sub-scale uses a 4-point Likert-type response options [3,4,13]. Each sub-scale is scored separately. Response choices for all items in the scale are summed and standardized to achieve a possible score of 0 to 100, with higher scores indicating better self-care and a score of 70 or greater as a cut point to judge self-care adequacy[13,14]. The cut point was found to be associated with the best 1-year event-free survival [14,15] and one half of a standard deviation, or an 8-point difference in the standardized score, was praised as a minimal clinically relevant change in scores[17].

Other instruments and measurements.

European Heart Failure Self-Care Behaviour Scale

Gr9-EHFScBS is a 5-point Likert scale, from 1 ("I completely agree") to 5 ("I do not agree at all"), that measures HF-related self-care behaviors. The total score is calculated by summing the ratings for each item. The total score ranges from 9 to 45 with higher scores indicating poorer self-care behaviors. Gr9-EHFScB is better supported by a one-factor[12], so it is suggested to be used as an uni-dimensional scale, while in parallel considering each item as a stand-alone aspect of self-care. Each item of EHFScBS was very well chosen by the researchers who created the instrument as it represents an important self-care behavior for the management of HF[7,18]. To assess the concurrent validity between Gr-SCHFI and Gr9-EHFScBS. Correlations between variables were examined with the Spearman linear correlation coefficient.

Translation and equivalence of the Greek version

Permission to use and translate the English version of SCHFI was obtained from the authors of the original questionnaire[13]. The process followed the classic approach of translation and back-translation[19]. Two bilingual cardiology nurses translated the questionnaire into Greek while two blinded bilingual cardiology nurses undertook the back-translation. A research team consisting of bilingual experts in cardiology nursing and heart failure nursing reviewed the differences of the back-translation in order to establish semantic equivalence. All the members of the team agreed to the final version. For assessing the readability of the final version, ten patients with HF were asked to appraise it. No difficulties were encountered in understanding or in explaining the items of the questionnaire.

Statistical Analysis

Descriptive statistics were used to describe demographic and clinical characteristics of the participants as well as to calculate central tendency and standard. Reliability and validity tests were employed to test the psychometric properties of the translated Greek version of the questionnaire.

The content validity was assessed by the research team (panel of experts) who evaluated the suitability of the Greek translation as previously described. Construct validity was assessed by performing a confirmatory factor analysis (CFA) to determine the dimensionality of the Greek version of the questionnaire in the dimensions of the questionnaire as proposed by the author of the instrument[2]. Spearman rank correlation coefficient was used to assess concurrent and discriminant validity between Gr-SCHFI and Gr9-EHFScBs. Both factor scores determinacy and Chronbach's alpha coefficients and test-retest (using a 15-day interval) were utilized to provide measures of internal consistency of the instrument and the composite reliability[20]. For the test-retest the Spearman r correlation coefficient was used.

Statistical analysis was performed in Rv. 4 [21] using the tidy verse suit of packages [22]. Confirmatory factor analysis was performed in the Lavaan package[23]. The minimum sample size was determined based on specific parameters (estimated fraction size, maximum error of the estimate, level of statistical significance, and size of general population)[24].

Ethical considerations

Signed license of use from the copyright holders of the questionnaire was ensured, in order to ensure the legal framework and cover by the copyright party. The study protocol was submitted and reviewed by the Ethics Committee of the university Departments and Clinics in Cyprus and Greece. Approvals were also granted by the Cyprus Bioethics Committee and the Cyprus Ministry of Health and all parties involved were informed about the study. Administration of all hospitals were informed and reviewed the study protocol, and agreed to the implementation of the study. The administration of each hospital reviewed the study protocol and agreed to the implementation of the study. The investigation conforms to the principles outlined in the Declaration of Helsinki.

All procedures-maintained confidentiality of participant personal data as instructed by GDPR Law. Participation in the study was voluntary, and participants provided a signed consent from after being informed about the details of the study who held no harm or risk for the participants.

RESULTS

Description of the sample

The demographic and the clinical characteristics of the 176 participants are presented in Table 1. The majority of the participants were male (78%), the mean age was 69 years (SD 11. 8) and married were the 73% of the participants. Regarding clinical severity patients 57% were classified as NYHA III , 39% as NYHA II, only 0.7% as NYHA I and 3,7% as NYHA IV. Most of the participants were living with their family (75%).

Table 1: Clinical and demographic characteristics

Characteristics	**N = 176**
Hospital	
Hospital 1 in Cyprus	3 (1.7%)
Hospital 2 in Cyprus	11 (6.25%)
Hospital 3 in Cyprus	22 (12.5%)
Hospital 4 in Cyprus	6 (3.4%)
University Hospital in Greece	134 (76%)
Sex	
Male	138 (78%)
Female	38 (22%)
Age - Mean (SD)	69 (11,8)
Unknown	5
Education	
Primary or nil	69 (47,4%)
High School	52 (35%)
Post-secondary education	12 (8.2%)
Higher education	1 (0.7%)
College or University education	13 (8.9%)
Unknown	29
Family status	
Divorced	17 (10%)
Unmarried	4 (2.4%)
Married	121 (73%)
Widower	24 (14%)
Unknown	10
NYHA	
I	1 (0.7%)
II	52 (39%)
III	76 (57%)
IV	5 (3.7%)
Unknown	42
Living status	
Lives with his/her family	127 (75%)
Lives home alone/with help from family	38 (22%)
Lives home alone/with domestic helper	4 (2.4%)
Unknown	7

Validity

Construct validity

CFA showed an acceptable fit[24] for the whole scale and the three scales (maintenance, management and self-confidence): RMSEA (0.07) [95% CI (0.06-0.08)], CFI (0.97), GFI (0.98), AGFI (0.98), NFI (0.95, TLI (0.97) and x^2 (181) =359.4, p value < 0.001 (Table 2).

Table 2. Confirmatory factor analysis (CFA) of the Greek Version of the Self – Care Management of Heart failure Index – (Gr-SCHFI)

Question	**Maintenance**	**Management**	**Confidence**
[1. Do you monitor your weight?]	0,59		
[2. Do you check your ankles for swelling?]	0,72		
[3. Do you try to avoid getting sick (e.g.)? (π.χ. flu vaccination, avoidance of sick people)]	0,69		
[4. Do you get some exercise?]	0,46		
[5. Do you keep your appointments with your doctor /nurse?]	0,83		
[6. Do you follow a low sodium diet?]	0,88		
[7.Do you get exercise for 30 minutes?]	0,61		
[8.Do you forget to take some of your prescribed medicines?]	0,53		
[9. Do you ask for low salt foods when visiting family and friends?]	0,77		
[10. Do you use a system or method to help you remember to take your medicines?	0,47		
[12Do you limit the salt you eat?]		0,88	
[13. Do you reduce your fluid intake?]		0,79	
[14. Do you take an extra diuretic medicine?]		0,86	
[15. Do you call your healthcare provider for guidance?]		0,92	
[16. Think of a treatment you used the last time you had symptoms. Did the treatment you used make you feel better?		0,26	
[1. Keep yourself stable and free of symptoms?]			0,77
[2Follow the treatment plan you have been given?]			0,96
[3Evaluate the importance of your symptoms?]			0,91
[4. Recognize changes in your health if they occur?]			0,87
[. 5Do something to relieve your symptoms?]			0,92
[6. Evaluate how well a remedy works?]			0,95
Composite Reliability	0,89	0,88	0,96
Cronbach's alpha	0,85	0,80	0,92
Goodness-of-fit			
Chi-Square (df)	359,4 (181)		
p-value	<0,001		
RMSE	0,07		
90% CI for RMSEA	(0,06 - 0,08)		
TLI	0,97		
NFI	0,95		
CFI	0,97		
GFI	0,98		
AGFI	0,98		

RMSEA, root mean square error of approximation; GFI, goodness-of-fit index; AGFI, adjusted goodness-of-fit index; TLI, Tucker Lewis Index;NFI, normed fit index; CFI comparative fit index.

Levels for an acceptable model fit: RMSEA≤0.08,TLI≥0.90;NFI≥0.90,CFI≥0.90.

Concurrent validity

Concurrent validity of the Gr-SCHFI was assessed by Spearman rank correlation coefficient between Gr-SCHFI and Gr9-EHFScBs (Lambrinou et al., 2014), which showed a strong correlation between the total scores of the two scales (r= 0.78, p<0.001) and their dimensions as well (Table 3). Distribution of all items' scores for all dimensions of both instruments are shown in Figures 1 and 2.

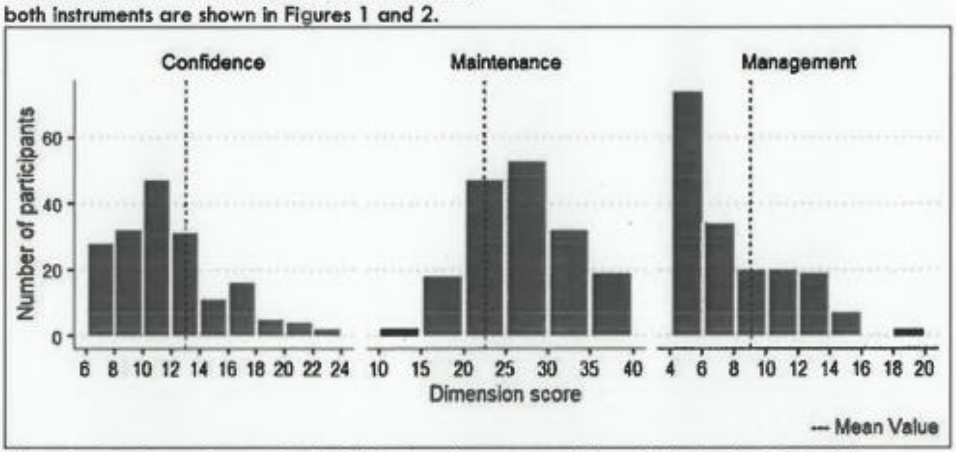

Figure 1. Distribution of scores for the Self – Care Management of Heart failure Index Gr9- SCHFI

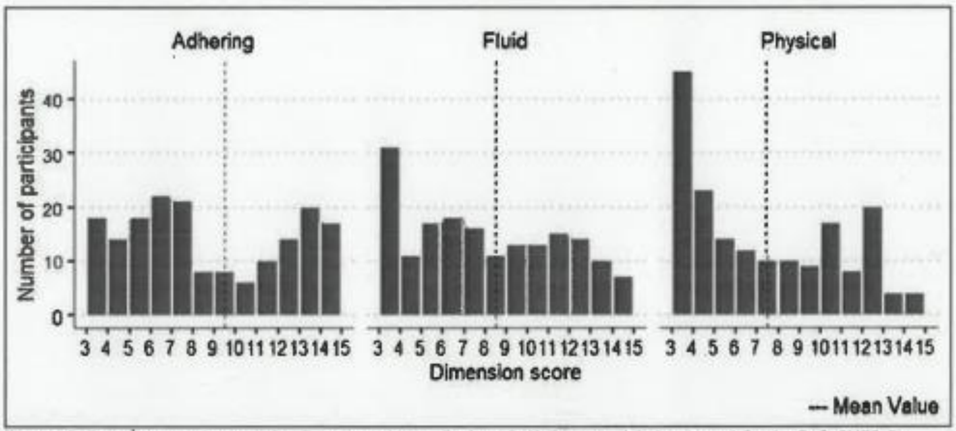

Figure 2. Distribution of scores for European Heart Failure Self Care and Behavioural Scale Gr9-EHFScBs

Reliability

Internal consistency

The CR in the level of Maintenance and Management were found to be 0,89 and 0,88, respectively, and in the level of Self-confidence was found to be 0,96; the values over 0,9 show are not accepted since they show that they measure the same item, and this is not a reliable constructive measure[24]. Only the item 16 was found to have a low CR (0.26); 'Think of a treatment you used the last time you had symptoms. Did the treatment you used make you feel better?'. Cronbach's alpha coefficients were found to be high: 0.9 for the whole scale, 0.89 for the dimension of Maintenance, 0.88 for the dimension of management and 0.92 for the dimension of confidence. All factors and reliability coefficients are presented in Table 2.

Test-retest reliability consistency was moderate to high with bivariate correlations ranging from 0.59 – 0.90 (Tables 3 and 4).

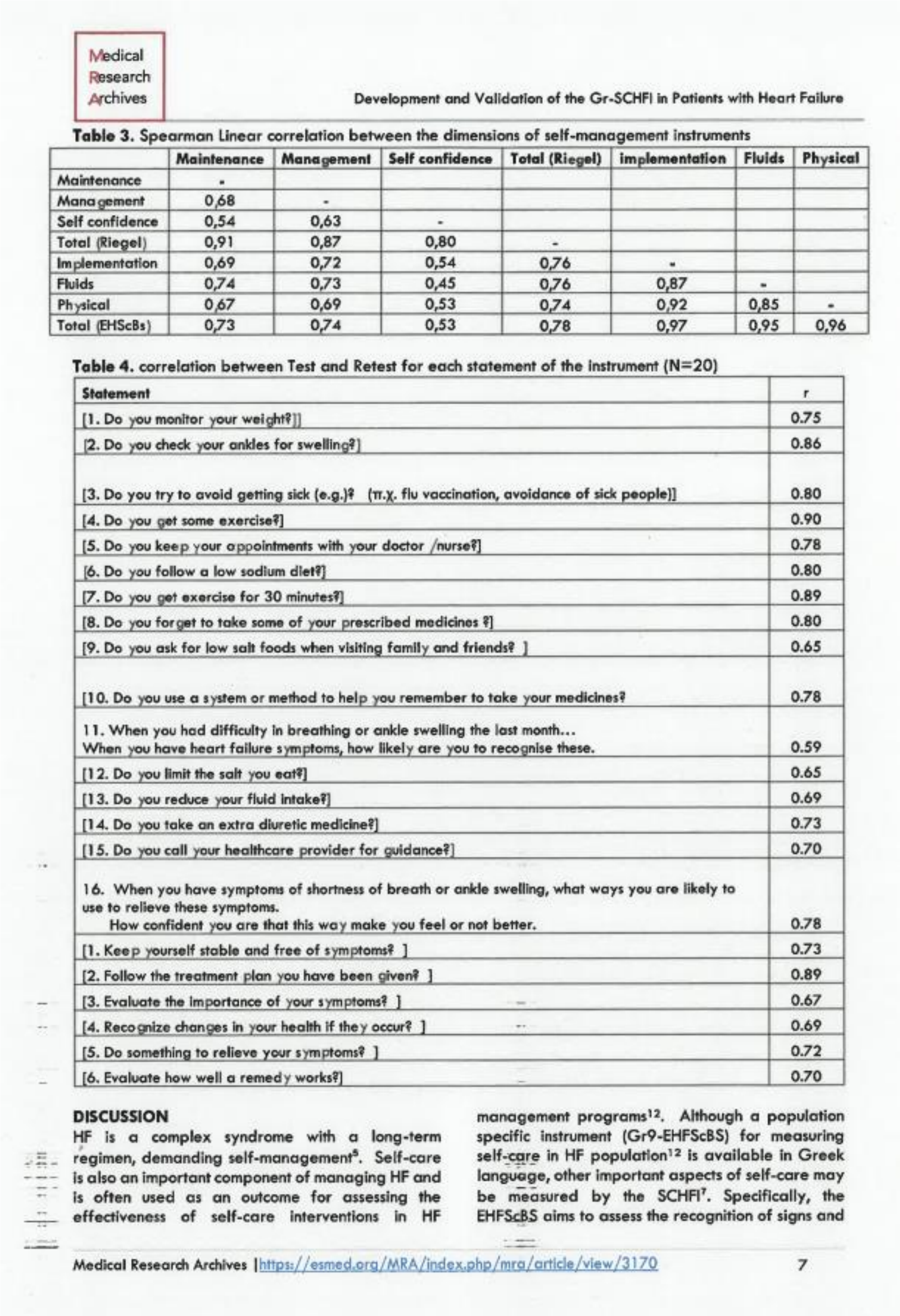

Table 3. Spearman Linear correlation between the dimensions of self-management instruments

	Maintenance	Management	Self confidence	Total (Riegel)	implementation	Fluids	Physical
Maintenance	-						
Management	0,68	-					
Self confidence	0,54	0,63	-				
Total (Riegel)	0,91	0,87	0,80	-			
Implementation	0,69	0,72	0,54	0,76	-		
Fluids	0,74	0,73	0,45	0,76	0,87	-	
Physical	0,67	0,69	0,53	0,74	0,92	0,85	-
Total (EHScBs)	0,73	0,74	0,53	0,78	0,97	0,95	0,96

Table 4. correlation between Test and Retest for each statement of the instrument (N=20)

Statement	r
[1. Do you monitor your weight?]]	0.75
[2. Do you check your ankles for swelling?]	0.86
[3. Do you try to avoid getting sick (e.g.)? (π.χ. flu vaccination, avoidance of sick people)]	0.80
[4. Do you get some exercise?]	0.90
[5. Do you keep your appointments with your doctor /nurse?]	0.78
[6. Do you follow a low sodium diet?]	0.80
[7. Do you get exercise for 30 minutes?]	0.89
[8. Do you forget to take some of your prescribed medicines ?]	0.80
[9. Do you ask for low salt foods when visiting family and friends?]	0.65
[10. Do you use a system or method to help you remember to take your medicines?	0.78
11. When you had difficulty in breathing or ankle swelling the last month… When you have heart failure symptoms, how likely are you to recognise these.	0.59
[12. Do you limit the salt you eat?]	0.65
[13. Do you reduce your fluid intake?]	0.69
[14. Do you take an extra diuretic medicine?]	0.73
[15. Do you call your healthcare provider for guidance?]	0.70
16. When you have symptoms of shortness of breath or ankle swelling, what ways you are likely to use to relieve these symptoms. How confident you are that this way make you feel or not better.	0.78
[1. Keep yourself stable and free of symptoms?]	0.73
[2. Follow the treatment plan you have been given?]	0.89
[3. Evaluate the importance of your symptoms?]	0.67
[4. Recognize changes in your health if they occur?]	0.69
[5. Do something to relieve your symptoms?]	0.72
[6. Evaluate how well a remedy works?]	0.70

DISCUSSION

HF is a complex syndrome with a long-term regimen, demanding self-management[5]. Self-care is also an important component of managing HF and is often used as an outcome for assessing the effectiveness of self-care interventions in HF management programs[12]. Although a population specific instrument (Gr9-EHFScBS) for measuring self-care in HF population[12] is available in Greek language, other important aspects of self-care may be measured by the SCHFI[7]. Specifically, the EHFScBS aims to assess the recognition of signs and symptoms of decompensation and decision-making in the occurrence of these symptoms, as SCHFI in addition evaluates the recognition and actions to improve the signs and symptoms of clinical deterioration and includes aspects related to how confident the individual feels to perform activities related to self-care[7]. Even though more recent factorial structure and changes on scorings of both instruments to make their use more international highlighted once again the differences in items of both instruments; suggesting scoring of dimensions should be done with caution. Similar conclusions were suggested by the authors of the Gr9-EHFScBS[12,25].

Confidence, a dimension included in SCHFI, is an important aspect of self-care; is a person's belief in his or her ability to perform a set of actions; the stronger these beliefs are in a person, the more likely he or she will initiate and continue activities that aid the attainment of a positive outcome[26]. Patients with HF often find it challenging to engage in numerous self-care behaviors that require ongoing commitment, alongside copying with comorbidities and daily living. Confidence in performing these self-care behaviors are central factors in facilitating lifestyle changes. Thus, improving HF patients' confidence, while considering their readiness to change, is a promising avenue for enhancing self-care capabilities[27,28]. Needing support for self-management to feel confident and take over such a responsibility is so obvious when patients with HF describe their needs[29]. Empowerment for self-care management is warranted during these unprecedented times and using plans for alternating methods of evaluation and therapeutic approaches to improve treatment of HF. Instruments including such aspects are necessary to identify obstacles and gaps for self-care management and gives the possibility to re-organize patient-centred care through telemonitoring (e.g.telephone)[11].

The CFA of the Gr - SCHFI showed acceptable adaption in all three dimensions; for maintenance adequate implementation (>0,46) and for the management (>0,79) apart from the question 16 (0,26). For the third dimension of confidence there was also good adaption (>0,77). The Gr-SCHFI showed more acceptable fit in all of the following indexes (RMSEA=0.07, GFI=0.98, AGFI=0.98, NFI=0,95, TLI=0,97, CFI = 0,97) compared to the Gr9-EHFScBs (RMSEA = 0.08, GFI = 0.92, AGFI = 0.87, NFI = 0.75 και CFI = 0.81). Regarding reliability, Chronbach's alpha was used on both questionnaires. In the Gr9-EHFScBs questionnaire overall Chronbach's alpha was low (0.66) as well as in its sub-dimensions (adhering to recommendations α=0.57, fluid and sodium management α=0.75, recognition of worsening of symptoms α=0.62), indicating a low internal consistency. The findings agree with the first validation of the instrument when researchers suggested to use the short instrument either as a sum, or each item separately[12]. In contrast, the Gr-SCHFI weighted questionnaire had satisfactory internal consistency indicators for the entire instrument (α = 0.90) and all the subdimensions (Maintenance α= 0.85, Management α=0.80, Confidence α= 0, 93). Only the item 16 ('Think of a treatment you used the last time you had symptoms. Did the treatment you used make you feel better?') of the dimension Management had low loading (0.26). The particular item shows similar issues of fit in most of the validations as it may fit to more than one dimensions; maintenance and management[4]. More specifically, in the current version of the instrument (SCHFI v6.2), symptom monitoring was included in the Self-Care Maintenance Scale and symptom recognition was captured in the Self-Care Management Scale. Previous psychometric studies[3,4] found that these two items were loaded in a single factor, providing evidence that symptom perception deserved more attention, something that changed in the more updated version (SCHFI v7.2)[30,31] . Authors used the SCHFI v6.2 as data collection started before the availability of the last update version (SCHFI v7.2). Based on qualitative studies, both maintenance and management of symptoms are difficult for patients with HF. They also need continuing supportive care for both. So what seems to be important is to support the patients for self-care management, exercise etc[29]. Moreover, is also significant to find out whether they have the confidence to establish and maintain self-care and self-management [28]. This was obvious during the pandemic where the access to health care services was difficult. Measuring confidence was crucial to recognize the patients who needed more support. Recruitment of patients in greater need was important and measuring confidence was a helpful indicator to recognize the patients that needed greater attention.

Additionally, the composite reliability factor was checked, indicating a high composite reliability index (CR = 0.89). The test- retest was used to weight the reliability of the instrument, showing a strong positive correlation in each statement. Specifically, the coefficient r ranged from the values r=0.59 - r=0.90 in each statement of the instrument and for the sub-dimensions (maintenance r = 0.89, management r=0.75 and confidence r=0.70). Current results are in linear with the Italian version of the instrument were the test- retest reliability showed moderate to high reliability coefficients (r = 0.64-0.89)[31]

A holistic approach of evaluation to care should target the management and treatment of all health concerns. Every patient brings his/her own complexity of comorbidities, sensitivity and contraindications to medications, cultural and health beliefs[11]. In the current era of pandemic, health professionals must have several instruments available to support continuing and distanced care, with clear lines and systems of communication, delegation and responsibility. By validating and comparing the Gr – SCHFI with the Gr9-EHFScBs questionnaire give the possibility to researchers and clinicians to use the instrument that is more convenient and appropriate each time and also combine them with other instruments in order to have a comprehensive reappraisal of the patient's condition and needs.

CONCLUSIONS

The Gr – SCHFI is a valid instrument and well adopted to Greek speaking populations even though has been validated before and accepted changes to newer versions. Its validation gives the opportunity of different kind of evaluations of patients with HF, even from a distance, during the pandemic period giving the possibility of person-centred approach and better management of a population which is at high risk for deterioration and acute events.

Implications to Nursing Practice:

- Validation and psychometric testing of the instrument SCHFI in Greek language, giving the opportunity to both; researchers and clinicians to use the questionnaire.
- Discussion and comparison of Gr-SCHFI and Gr9-EHFScBs, helping researchers and clinicians to select each time the most appropriate instrument based on the purpose.
- Highlights the possibility of long-distance patient's evaluation using self-administrated instruments of self-care management.
-

CONFLICT OF INTEREST

Nothing to be declared.

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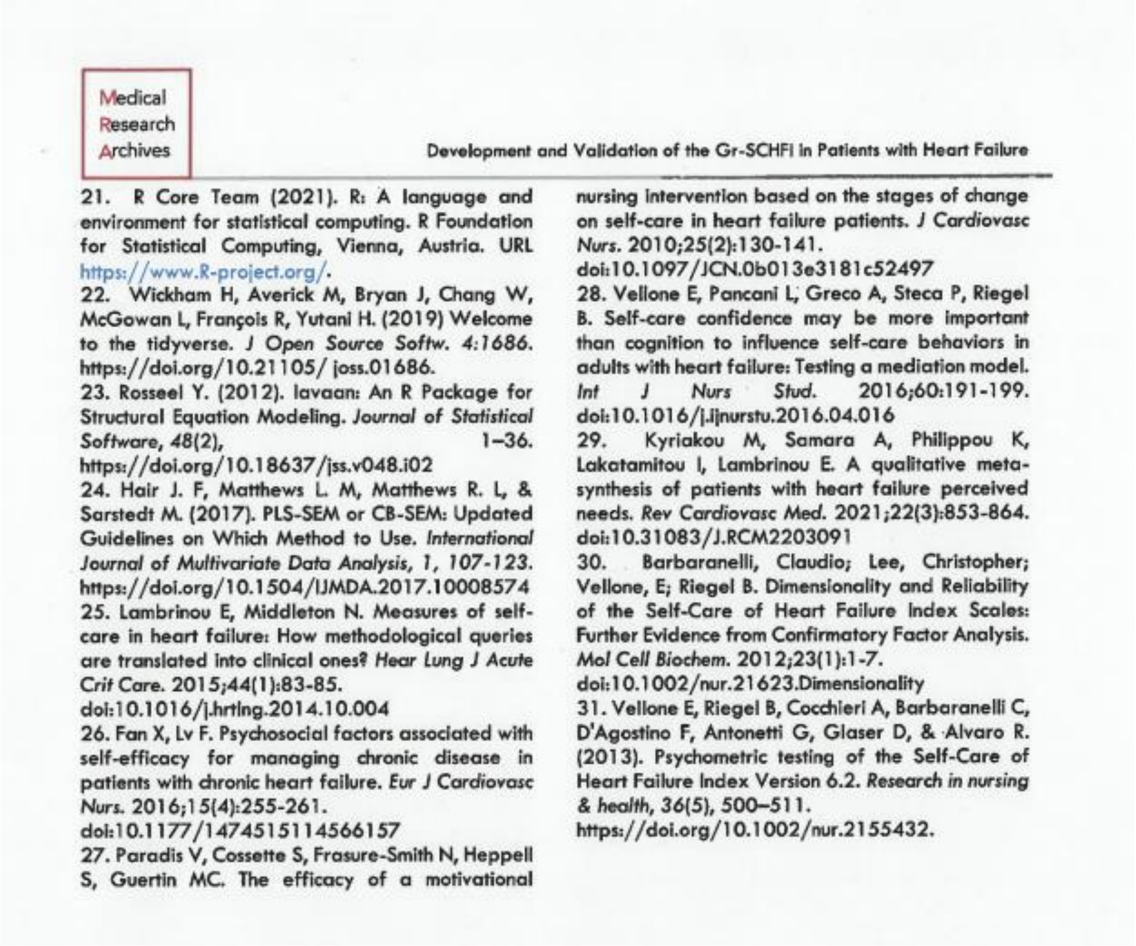

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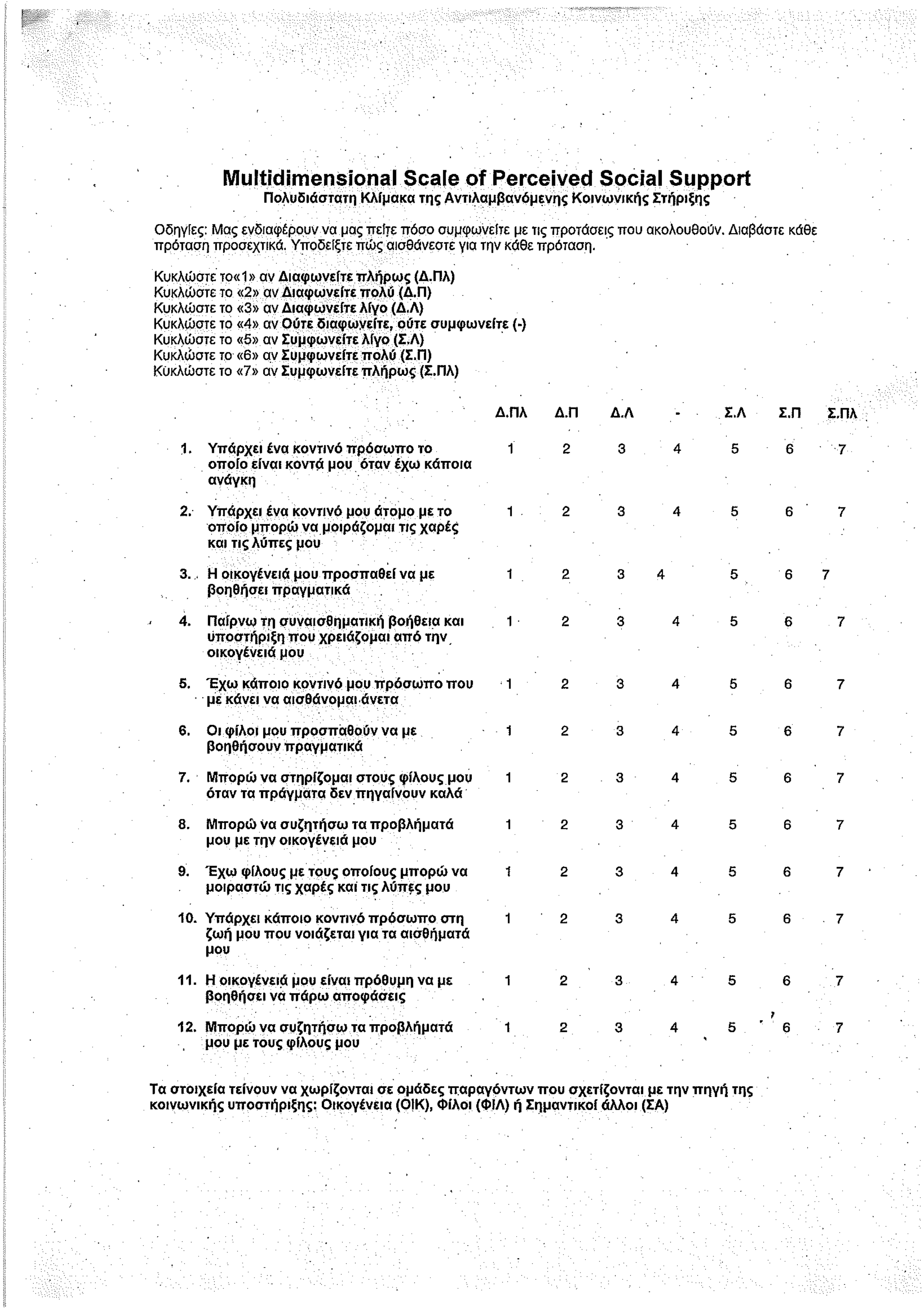
APPENDIX XVI



Multidimensional Scale of Perceived Social Support

Πολυδιάστατη Κλίμακα της Αντιλαμβανόμενης Κοινωνικής Στήριξης

Οδηγίες: Μας ενδιαφέρουν να μας πείτε πόσο συμφωνείτε με τις προτάσεις που ακολουθούν. Διαβάστε κάθε πρόταση προσεχτικά. Υποδείξτε πώς αισθάνεστε για την κάθε πρόταση.

Κυκλώστε το«1» αν **Διαφωνείτε πλήρως (Δ.Πλ)**
Κυκλώστε το «2» αν **Διαφωνείτε πολύ (Δ.Π)**
Κυκλώστε το «3» αν **Διαφωνείτε λίγο (Δ.Λ)**
Κυκλώστε το «4» αν **Ούτε διαφωνείτε, ούτε συμφωνείτε (-)**
Κυκλώστε το «5» αν **Συμφωνείτε λίγο (Σ.Λ)**
Κυκλώστε το «6» αν **Συμφωνείτε πολύ (Σ.Π)**
Κυκλώστε το «7» αν **Συμφωνείτε πλήρως (Σ.Πλ)**

		Δ.Πλ	**Δ.Π**	**Δ.Λ**	**-**	**Σ.Λ**	**Σ.Π**	**Σ.Πλ**
1.	**Υπάρχει ένα κοντινό πρόσωπο το οποίο είναι κοντά μου όταν έχω κάποια ανάγκη**	1	2	3	4	5	6	7
2.	**Υπάρχει ένα κοντινό μου άτομο με το οποίο μπορώ να μοιράζομαι τις χαρές και τις λύπες μου**	1	2	3	4	5	6	7
3.	**Η οικογένειά μου προσπαθεί να με βοηθήσει πραγματικά**	1	2	3	4	5	6	7
4.	**Παίρνω τη συναισθηματική βοήθεια και υποστήριξη που χρειάζομαι από την οικογένειά μου**	1	2	3	4	5	6	7
5.	**Έχω κάποιο κοντινό μου πρόσωπο που με κάνει να αισθάνομαι άνετα**	1	2	3	4	5	6	7
6.	**Οι φίλοι μου προσπαθούν να με βοηθήσουν πραγματικά**	1	2	3	4	5	6	7
7.	**Μπορώ να στηρίζομαι στους φίλους μου όταν τα πράγματα δεν πηγαίνουν καλά**	1	2	3	4	5	6	7
8.	**Μπορώ να συζητήσω τα προβλήματά μου με την οικογένειά μου**	1	2	3	4	5	6	7
9.	**Έχω φίλους με τους οποίους μπορώ να μοιραστώ τις χαρές και τις λύπες μου**	1	2	3	4	5	6	7
10.	**Υπάρχει κάποιο κοντινό πρόσωπο στη ζωή μου που νοιάζεται για τα αισθήματά μου**	1	2	3	4	5	6	7
11.	**Η οικογένειά μου είναι πρόθυμη να με βοηθήσει να πάρω αποφάσεις**	1	2	3	4	5	6	7
12.	**Μπορώ να συζητήσω τα προβλήματά μου με τους φίλους μου**	1	2	3	4	5	6	7

Τα στοιχεία τείνουν να χωρίζονται σε ομάδες παραγόντων που σχετίζονται με την πηγή της κοινωνικής υποστήριξης: Οικογένεια (ΟΙΚ), Φίλοι (ΦΙΛ) ή Σημαντικοί άλλοι (ΣΑ)

APPENDIX XVII

European Heart Failure Self-Care
Behaviour Scale

(Ευρωπαϊκή Κλίμακα για τη Συμπεριφορά Αυτοφροντίδας στην Καρδιακή Ανεπάρκεια)

Η κλίμακα αυτή περιέχει θέματα που αφορούν στην αυτοφροντίδα ατόμων με καρδιακή ανεπάρκεια. Απαντήστε σε κάθε πρόταση που ακολουθεί κυκλώνοντας τον αριθμό που πιστεύετε ότι αντιπροσωπεύει καλύτερα την κατάστασή σας. Οι διάφορες απαντήσεις αποτελούν μια κλίμακα που εκτείνεται από το «Συμφωνώ πλήρως» (1) μέχρι το «Διαφωνώ πλήρως» (5). Ακόμα και αν δεν είστε σίγουρος/ή για μια συγκεκριμένη πρόταση, κυκλώστε τον αριθμό που νιώθετε ότι σας αντιπροσωπεύει πιο καλά

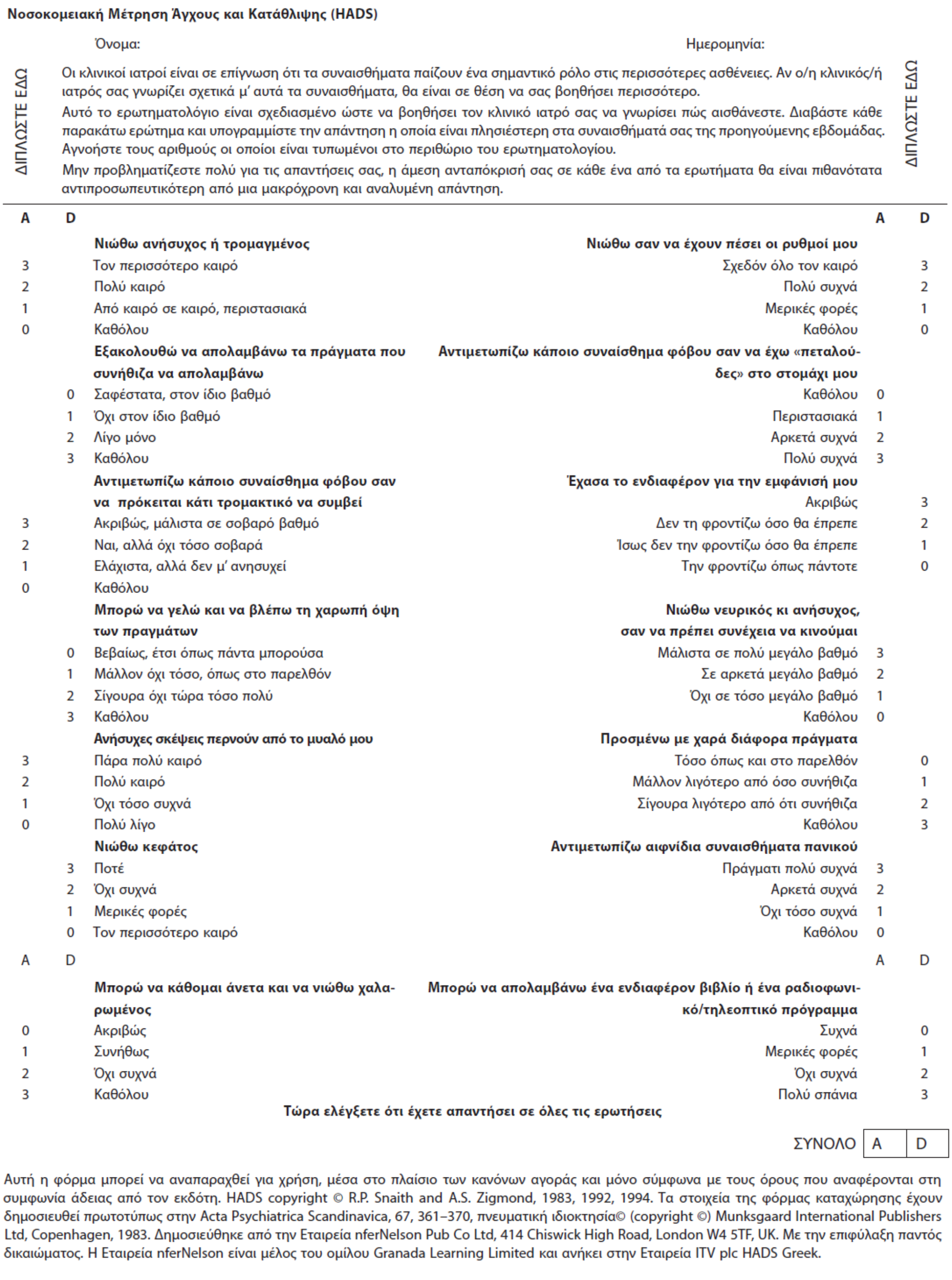
	Συμφωνώ πλήρως				**Διαφωνώ πλήρως**
1. Ζυγίζομαι καθημερινά	**1**	**2**	**3**	**4**	**5**
2. Αν αυξηθεί η δύσπνοιά μου επικοινωνώ με το γιατρό μου ή το νοσηλευτή	**1**	**2**	**3**	**4**	**5**
3. Αν τα πόδια μου πρηστούν περισσότερο από ότι συνήθως, επικοινωνώ με το γιατρό ή το νοσηλευτή	**1**	**2**	**3**	**4**	**5**
	1	**2**	**3**	**4**	**5**

4. Αν πάρω 2 κιλά σε μια βδομάδα, επικοινωνώ με το γιατρό ή το νοσηλευτή					
5. Περιορίζω την ποσότητα των υγρών που παίρνω (όχι περισσότερο από 1.5 – 2 λίτρα την ημέρα)	**1**	**2**	**3**	**4**	**5**
6. Αν αισθανθώ μεγάλη κόπωση, επικοινωνώ με το γιατρό ή το νοσηλευτή	**1**	**2**	**3**	**4**	**5**
7. Ακολουθώ δίαιτα με λίγο αλάτι	**1**	**2**	**3**	**4**	**5**
8. Παίρνω τα φάρμακά μου σύμφωνα με τις ιατρικές οδηγίες	**1**	**2**	**3**	**4**	**5**
9. Ασκούμαι τακτικά	**1**	**2**	**3**	**4**	**5**

Ανάπτυξη της κλίμακας και copyrights:

Jaarsma T, Stromberg A, Martensson J, Dracup K. Development and testing of the European Heart Failure Self-Care Behaviour Scale. Eur J Heart Fail. 2003; 5:363-70

APPENDIX XVIII



Νοσοκομειακή Μέτρηση Άγχους και Κατάθλιψης (HADS)

Όνομα: Ημερομηνία:

ΔΙΠΛΩΣΤΕ ΕΔΩ

Οι κλινικοί ιατροί είναι σε επίγνωση ότι τα συναισθήματα παίζουν ένα σημαντικό ρόλο στις περισσότερες ασθένειες. Αν ο/η κλινικός/ή ιατρός σας γνωρίζει σχετικά μ' αυτά τα συναισθήματα, θα είναι σε θέση να σας βοηθήσει περισσότερο.

Αυτό το ερωτηματολόγιο είναι σχεδιασμένο ώστε να βοηθήσει τον κλινικό ιατρό σας να γνωρίσει πώς αισθάνεστε. Διαβάστε κάθε παρακάτω ερώτημα και υπογραμμίστε την απάντηση η οποία είναι πλησιέστερη στα συναισθήματά σας της προηγούμενης εβδομάδας. Αγνοήστε τους αριθμούς οι οποίοι είναι τυπωμένοι στο περιθώριο του ερωτηματολογίου.

Μην προβληματίζεστε πολύ για τις απαντήσεις σας, η άμεση ανταπόκρισή σας σε κάθε ένα από τα ερωτήματα θα είναι πιθανότατα αντιπροσωπευτικότερη από μια μακρόχρονη και αναλυμένη απάντηση.

ΔΙΠΛΩΣΤΕ ΕΔΩ

A	D			A	D
		Νιώθω ανήσυχος ή τρομαγμένος	**Νιώθω σαν να έχουν πέσει οι ρυθμοί μου**		
3		Τον περισσότερο καιρό	Σχεδόν όλο τον καιρό		3
2		Πολύ καιρό	Πολύ συχνά		2
1		Από καιρό σε καιρό, περιστασιακά	Μερικές φορές		1
0		Καθόλου	Καθόλου		0
		Εξακολουθώ να απολαμβάνω τα πράγματα που συνήθιζα να απολαμβάνω	**Αντιμετωπίζω κάποιο συναίσθημα φόβου σαν να έχω «πεταλούδες» στο στομάχι μου**		
	0	Σαφέστατα, στον ίδιο βαθμό	Καθόλου	0	
	1	Όχι στον ίδιο βαθμό	Περιστασιακά	1	
	2	Λίγο μόνο	Αρκετά συχνά	2	
	3	Καθόλου	Πολύ συχνά	3	
		Αντιμετωπίζω κάποιο συναίσθημα φόβου σαν να πρόκειται κάτι τρομακτικό να συμβεί	**Έχασα το ενδιαφέρον για την εμφάνισή μου**		
3		Ακριβώς, μάλιστα σε σοβαρό βαθμό	Ακριβώς		3
2		Ναι, αλλά όχι τόσο σοβαρά	Δεν τη φροντίζω όσο θα έπρεπε		2
1		Ελάχιστα, αλλά δεν μ' ανησυχεί	Ίσως δεν την φροντίζω όσο θα έπρεπε		1
0		Καθόλου	Την φροντίζω όπως πάντοτε		0
		Μπορώ να γελώ και να βλέπω τη χαρωπή όψη των πραγμάτων	**Νιώθω νευρικός κι ανήσυχος, σαν να πρέπει συνέχεια να κινούμαι**		
	0	Βεβαίως, έτσι όπως πάντα μπορούσα	Μάλιστα σε πολύ μεγάλο βαθμό	3	
	1	Μάλλον όχι τόσο, όπως στο παρελθόν	Σε αρκετά μεγάλο βαθμό	2	
	2	Σίγουρα όχι τώρα τόσο πολύ	Όχι σε τόσο μεγάλο βαθμό	1	
	3	Καθόλου	Καθόλου	0	
		Ανήσυχες σκέψεις περνούν από το μυαλό μου	**Προσμένω με χαρά διάφορα πράγματα**		
3		Πάρα πολύ καιρό	Τόσο όπως και στο παρελθόν		0
2		Πολύ καιρό	Μάλλον λιγότερο από όσο συνήθιζα		1
1		Όχι τόσο συχνά	Σίγουρα λιγότερο από ότι συνήθιζα		2
0		Πολύ λίγο	Καθόλου		3
		Νιώθω κεφάτος	**Αντιμετωπίζω αιφνίδια συναισθήματα πανικού**		
	3	Ποτέ	Πράγματι πολύ συχνά	3	
	2	Όχι συχνά	Αρκετά συχνά	2	
	1	Μερικές φορές	Όχι τόσο συχνά	1	
	0	Τον περισσότερο καιρό	Καθόλου	0	
A	D			A	D
		Μπορώ να κάθομαι άνετα και να νιώθω χαλαρωμένος	**Μπορώ να απολαμβάνω ένα ενδιαφέρον βιβλίο ή ένα ραδιοφωνικό/τηλεοπτικό πρόγραμμα**		
0		Ακριβώς	Συχνά		0
1		Συνήθως	Μερικές φορές		1
2		Όχι συχνά	Όχι συχνά		2
3		Καθόλου	Πολύ σπάνια		3

Τώρα ελέγξετε ότι έχετε απαντήσει σε όλες τις ερωτήσεις

ΣΥΝΟΛΟ | A | D |

APPENDIX XIX

International Physical Activity Questionnaire*

Short - self answered - 8 items

Greek Version**

Οι παρακάτω ερωτήσεις αφορούν στο χρόνο που έχετε αφιερώσει για κάποια σωματική δραστηριότητα τις **<u>τελευταίες 7 ημέρες</u>**. Περιλαμβάνουν ερωτήσεις σχετικά με δραστηριότητες που κάνετε κατά την εργασία σας, στις μετακινήσεις σας, στις δουλειές του σπιτιού, του κήπου και στον ελεύθερο χρόνο σας για ψυχαγωγία, άσκηση ή άθληση. Σας παρακαλώ να απαντήσετε όλες τις ερωτήσεις, ακόμα και εάν πιστεύετε ότι δεν είστε ένα ιδιαίτερα σωματικά δραστήριο άτομο.

Πριν απαντήσετε τις ερωτήσεις 1 και 2, σκεφτείτε όλες τις **<u>έντονες</u>** σωματικές δραστηριότητες που κάνατε κατά τις **<u>τελευταίες 7 ημέρες</u>**. Μια έντονη σωματική δραστηριότητα αναφέρεται σε δραστηριότητες που απαιτούν έντονη σωματική προσπάθεια και σας κάνουν να αναπνέετε σημαντικά δυσκολότερα από ότι συνήθως. Σκεφθείτε μόνο τις **<u>έντονες</u>** σωματικές δραστηριότητες που κάνατε και είχαν διάρκεια **<u>μεγαλύτερη από 10 λεπτά</u>** κάθε φορά.

1. **Κατά τις τελευταίες 7 ημέρες, πόσες ημέρες κάνατε κάποια έντονη σωματική δραστηριότητα, όπως σκάψιμο, έντονη άσκηση με βάρη, τρέξιμο σε διάδρομο με κλίση, γρήγορο τρέξιμο, aerobics, γρήγορη ποδηλασία, γρήγορη κολύμβηση, τένις μονό, αγώνας σε γήπεδο (ποδόσφαιρο, basketball-μπάσκετ, volleyball-βόλεϊ, κλπ);**

_____ ημέρες ανά εβδομάδα

☐ εάν δεν κάνατε έντονες σωματικές δραστηριότητες,
τότε προχωρήστε στην ερώτηση 3

2. **Τις ημέρες που κάνατε κάποια έντονη σωματική δραστηριότητα, πόσο χρόνο αφιερώνατε συνήθως;**

_____ λεπτά ανά ημέρα δεν γνωρίζω/δεν είμαι βέβαιος ☐

Πριν απαντήσετε τις ερωτήσεις 3 και 4, σκεφτείτε όλες τις **μέτριας έντασης** σωματικές δραστηριότητες που κάνατε κατά τις **τελευταίες 7 ημέρες**. Μια μέτριας έντασης σωματική δραστηριότητα αναφέρεται σε δραστηριότητες που απαιτούν μέτρια σωματική προσπάθεια και σας κάνουν να αναπνέετε κάπως δυσκολότερα από ότι συνήθως. Σκεφθείτε μόνο τις **μέτριας έντασης** σωματικές δραστηριότητές που κάνατε και είχαν διάρκεια **μεγαλύτερη από 10 λεπτά** κάθε φορά.

* The IPAQ group: https://sites.google.com/site/theipaq/home

** Papathanasiou G, et al. *Hellenic J Cardiol*. 2009; 50: 283-294.

3. **Κατά τις τελευταίες 7 ημέρες, πόσες ημέρες κάνατε κάποια μέτρια σωματική δραστηριότητα, όπως το να σηκώσετε και να μεταφέρετε ελαφρά βάρη (λιγότερο από 10 κιλά), συνολική καθαριότητα του σπιτιού, ήπιες ρυθμικές ασκήσεις σώματος, ποδηλασία αναψυχής με χαμηλή ταχύτητα, χαλαρή κολύμβηση; Σας παρακαλώ να μη συμπεριλάβετε το περπάτημα.**

_____ ημέρες ανά εβδομάδα

☐ εάν δεν κάνατε μέτριας έντασης σωματικές δραστηριότητες,

τότε προχωρήστε στην ερώτηση 5

4. **Τις ημέρες που κάνατε κάποια μέτρια σωματική δραστηριότητα, πόσο χρόνο αφιερώνατε συνήθως;**

_____ λεπτά ανά ημέρα δεν γνωρίζω/δεν είμαι βέβαιος ☐

Πριν απαντήσετε στις ερωτήσεις 5 και 6, σκεφτείτε το χρόνο που περπατήσατε κατά τις **τελευταίες 7 ημέρες**. Να συμπεριλάβετε το περπάτημα στο χώρο της εργασίας σας, στο σπίτι, στις μετακινήσεις σας και στον ελεύθερο χρόνο σας για ψυχαγωγία, άσκηση ή άθληση.

5. **Κατά τις τελευταίες 7 ημέρες, πόσες ημέρες περπατήσατε για περισσότερο από 10 συνεχόμενα λεπτά;**

_____ ημέρες ανά εβδομάδα

☐ εάν δεν περπατήσατε καμία φορά περισσότερο από 10 συνεχόμενα λεπτά, τότε προχωρήστε στην ερώτηση 7

6. **Τις ημέρες που περπατήσατε, για περισσότερο από 10 συνεχόμενα λεπτά, πόσο χρόνο περάσατε περπατώντας;**

_____ λεπτά ανά ημέρα δεν γνωρίζω/δεν είμαι βέβαιος ☐

7. **Κατά τις τελευταίες 7 ημέρες, πόσο χρόνο περάσατε καθισμένος/η σε μια συνηθισμένη μέρα; Ο χρόνος αυτός μπορεί να περιλαμβάνει το χρόνο που περνάτε καθισμένος/η στο σπίτι, στο γραφείο, στο αυτοκίνητο, όταν διαβάζετε, όταν είστε με φίλους, ξεκουράζεστε σε πολυθρόνα ή βλέπετε τηλεόραση, αλλά δεν περιλαμβάνει τον ύπνο.**

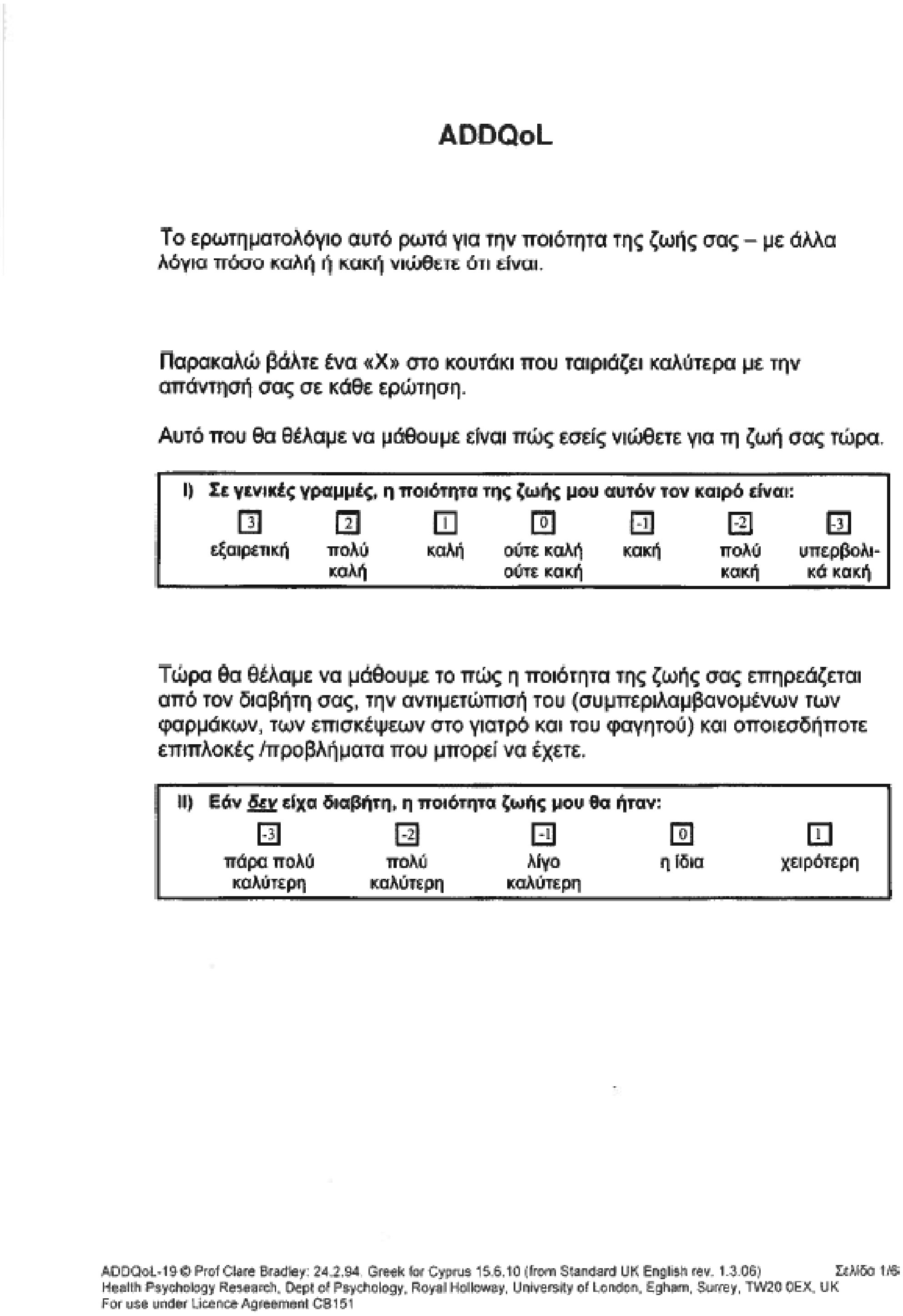
_____ ώρες ανά ημέρα δεν γνωρίζω/δεν είμαι βέβαιος ☐

8. Κατά τις τελευταίες 7 ημέρες, ποια ήταν η ένταση της σωματικής δραστηριότητας που κάνατε;

	Έντονη	**Μέτρια**	**Χαμηλή**	**Δεν γνωρίζω**
1. στην εργασία (δουλειά)				
2. στις μετακινήσεις				
3. στις δουλειές μέσα στο σπίτι και γύρω από αυτό (συμπεριλαμβανομένου του νοικοκυριού, της κηπουρικής, των γενικών επισκευών ή τη φροντίδα της οικογένειας)				
4. για ψυχαγωγία, άθληση και δραστηριότητες ελεύθερου χρόνου				

Τέλος του ερωτηματολογίου. Σας ευχαριστούμε για τη συμμετοχή σας.

APPENDIX XX



ADDQoL

Το ερωτηματολόγιο αυτό ρωτά για την ποιότητα της ζωής σας – με άλλα λόγια πόσο καλή ή κακή νιώθετε ότι είναι.

Παρακαλώ βάλτε ένα «Χ» στο κουτάκι που ταιριάζει καλύτερα με την απάντησή σας σε κάθε ερώτηση.

Αυτό που θα θέλαμε να μάθουμε είναι πώς εσείς νιώθετε για τη ζωή σας τώρα.

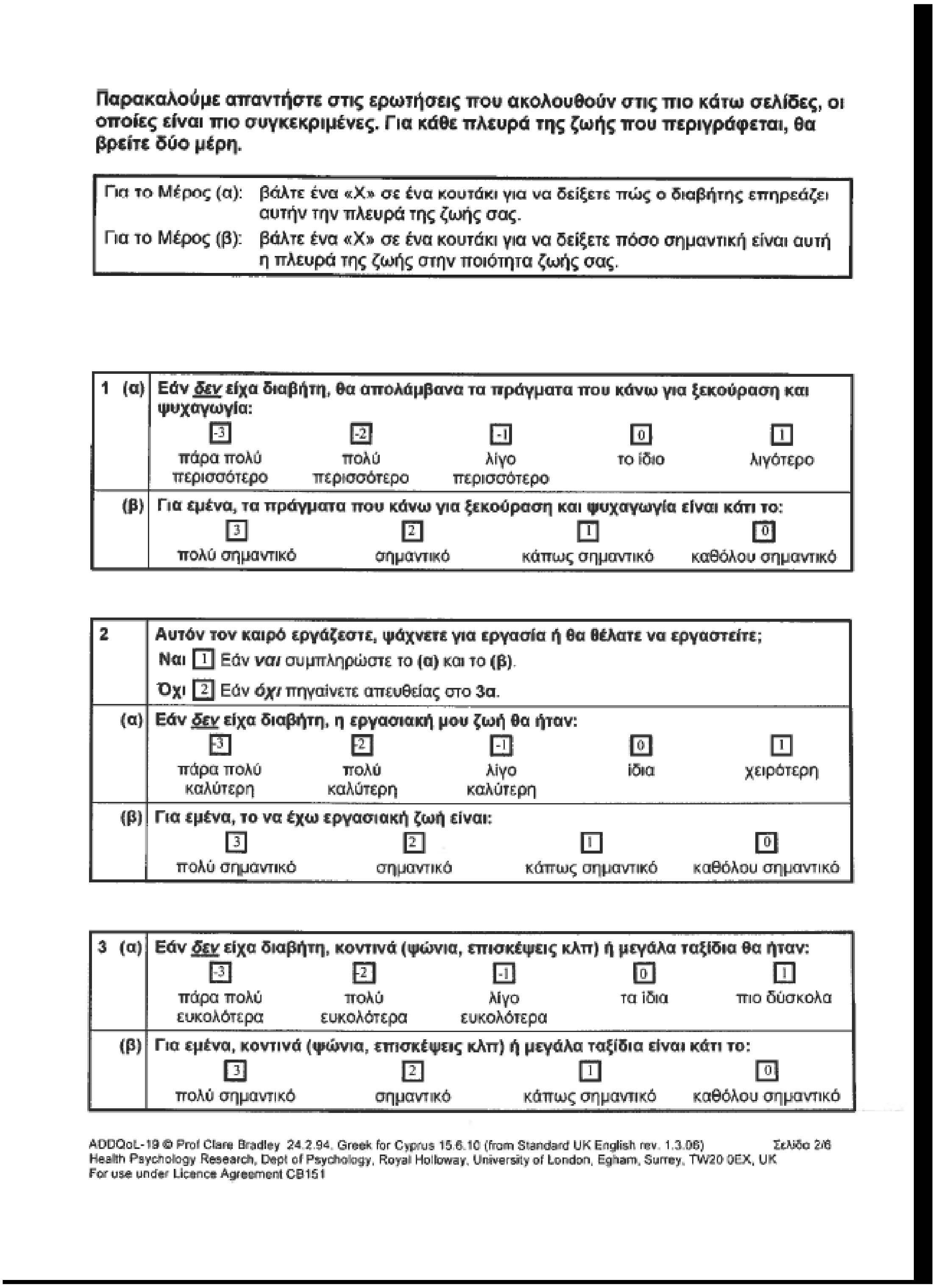
I) Σε γενικές γραμμές, η ποιότητα της ζωής μου αυτόν τον καιρό είναι:

3	2	1	0	-1	-2	-3
εξαιρετική	πολύ καλή	καλή	ούτε καλή ούτε κακή	κακή	πολύ κακή	υπερβολικά κακή

Τώρα θα θέλαμε να μάθουμε το πώς η ποιότητα της ζωής σας επηρεάζεται από τον διαβήτη σας, την αντιμετώπισή του (συμπεριλαμβανομένων των φαρμάκων, των επισκέψεων στο γιατρό και του φαγητού) και οποιεσδήποτε επιπλοκές /προβλήματα που μπορεί να έχετε.

II) Εάν δεν είχα διαβήτη, η ποιότητα ζωής μου θα ήταν:

-3	-2	-1	0	1
πάρα πολύ καλύτερη	πολύ καλύτερη	λίγο καλύτερη	η ίδια	χειρότερη



Παρακαλούμε απαντήστε στις ερωτήσεις που ακολουθούν στις πιο κάτω σελίδες, οι οποίες είναι πιο συγκεκριμένες. Για κάθε πλευρά της ζωής που περιγράφεται, θα βρείτε δύο μέρη.

Για το Μέρος (α):	βάλτε ένα «Χ» σε ένα κουτάκι για να δείξετε πώς ο διαβήτης επηρεάζει αυτήν την πλευρά της ζωής σας.
Για το Μέρος (β):	βάλτε ένα «Χ» σε ένα κουτάκι για να δείξετε πόσο σημαντική είναι αυτή η πλευρά της ζωής στην ποιότητα ζωής σας.

1 (α) **Εάν *δεν* είχα διαβήτη, θα απολάμβανα τα πράγματα που κάνω για ξεκούραση και ψυχαγωγία:**

☐ -3	☐ -2	☐ -1	☐ 0	☐ 1
πάρα πολύ περισσότερο	πολύ περισσότερο	λίγο περισσότερο	το ίδιο	λιγότερο

(β) **Για εμένα, τα πράγματα που κάνω για ξεκούραση και ψυχαγωγία είναι κάτι το:**

☐ 3	☐ 2	☐ 1	☐ 0
πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό

2 **Αυτόν τον καιρό εργάζεστε, ψάχνετε για εργασία ή θα θέλατε να εργαστείτε;**

Ναι ☐ 1 Εάν ***ναι*** συμπληρώστε το **(α)** και το **(β)**.

Όχι ☐ 2 Εάν ***όχι*** πηγαίνετε απευθείας στο **3α**.

(α) **Εάν *δεν* είχα διαβήτη, η εργασιακή μου ζωή θα ήταν:**

☐ -3	☐ -2	☐ -1	☐ 0	☐ 1
πάρα πολύ καλύτερη	πολύ καλύτερη	λίγο καλύτερη	ίδια	χειρότερη

(β) **Για εμένα, το να έχω εργασιακή ζωή είναι:**

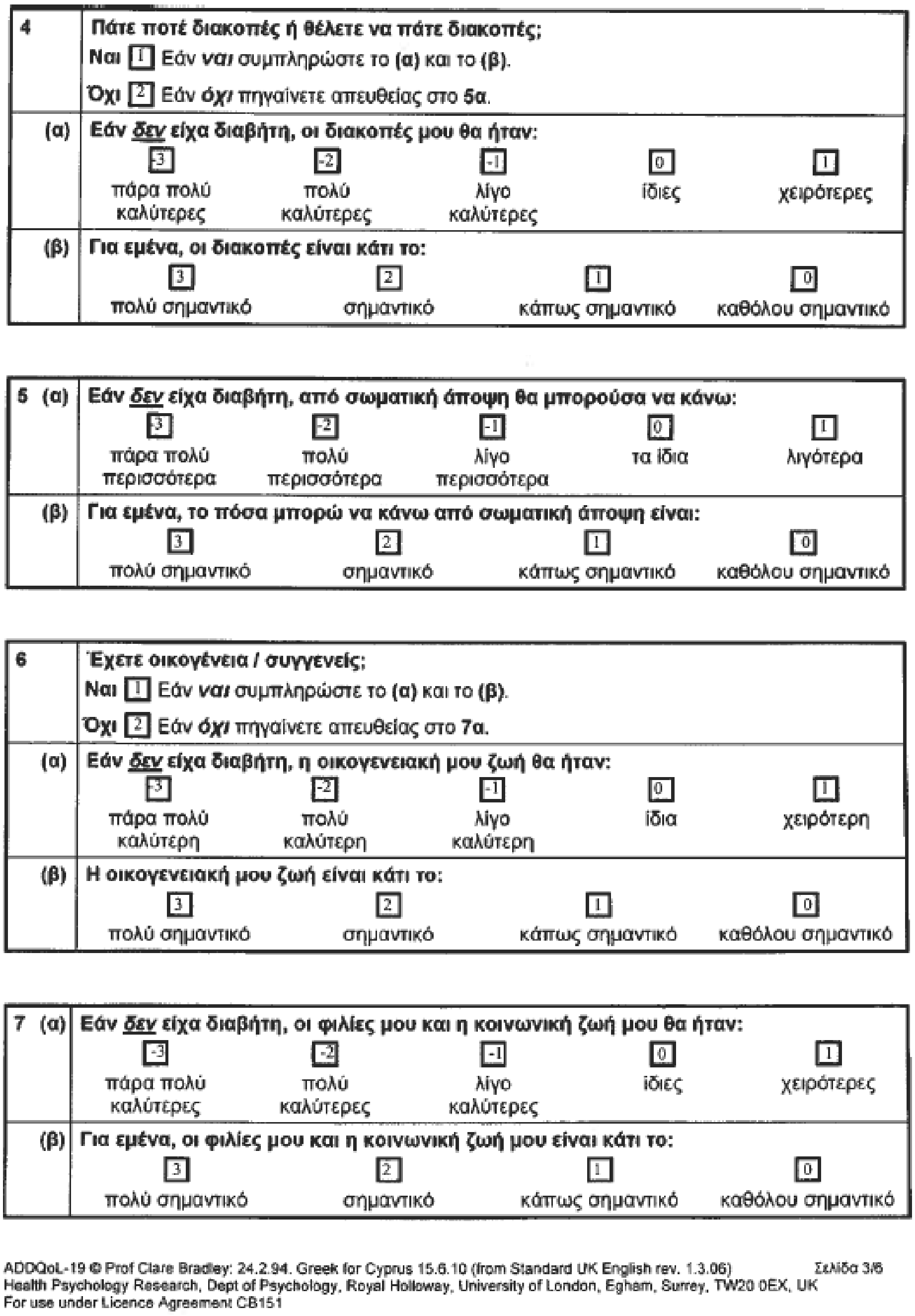
☐ 3	☐ 2	☐ 1	☐ 0
πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό

3 (α) **Εάν *δεν* είχα διαβήτη, κοντινά (ψώνια, επισκέψεις κλπ) ή μεγάλα ταξίδια θα ήταν:**

☐ -3	☐ -2	☐ -1	☐ 0	☐ 1
πάρα πολύ ευκολότερα	πολύ ευκολότερα	λίγο ευκολότερα	τα ίδια	πιο δύσκολα

(β) **Για εμένα, κοντινά (ψώνια, επισκέψεις κλπ) ή μεγάλα ταξίδια είναι κάτι το:**

☐ 3	☐ 2	☐ 1	☐ 0
πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό



4 **Πάτε ποτέ διακοπές ή θέλετε να πάτε διακοπές;**
Ναι [1] Εάν ***ναι*** συμπληρώστε το **(α)** και το **(β)**.
Όχι [2] Εάν ***όχι*** πηγαίνετε απευθείας στο **5α**.

(α) **Εάν *δεν* είχα διαβήτη, οι διακοπές μου θα ήταν:**

-3	-2	-1	0	1
πάρα πολύ καλύτερες	πολύ καλύτερες	λίγο καλύτερες	ίδιες	χειρότερες

(β) **Για εμένα, οι διακοπές είναι κάτι το:**

3	2	1	0
πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό

5 (α) **Εάν *δεν* είχα διαβήτη, από σωματική άποψη θα μπορούσα να κάνω:**

-3	-2	-1	0	1
πάρα πολύ περισσότερα	πολύ περισσότερα	λίγο περισσότερα	τα ίδια	λιγότερα

(β) **Για εμένα, το πόσα μπορώ να κάνω από σωματική άποψη είναι:**

3	2	1	0
πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό

6 **Έχετε οικογένεια / συγγενείς;**
Ναι [1] Εάν ***ναι*** συμπληρώστε το **(α)** και το **(β)**.
Όχι [2] Εάν ***όχι*** πηγαίνετε απευθείας στο **7α**.

(α) **Εάν *δεν* είχα διαβήτη, η οικογενειακή μου ζωή θα ήταν:**

-3	-2	-1	0	1
πάρα πολύ καλύτερη	πολύ καλύτερη	λίγο καλύτερη	ίδια	χειρότερη

(β) **Η οικογενειακή μου ζωή είναι κάτι το:**

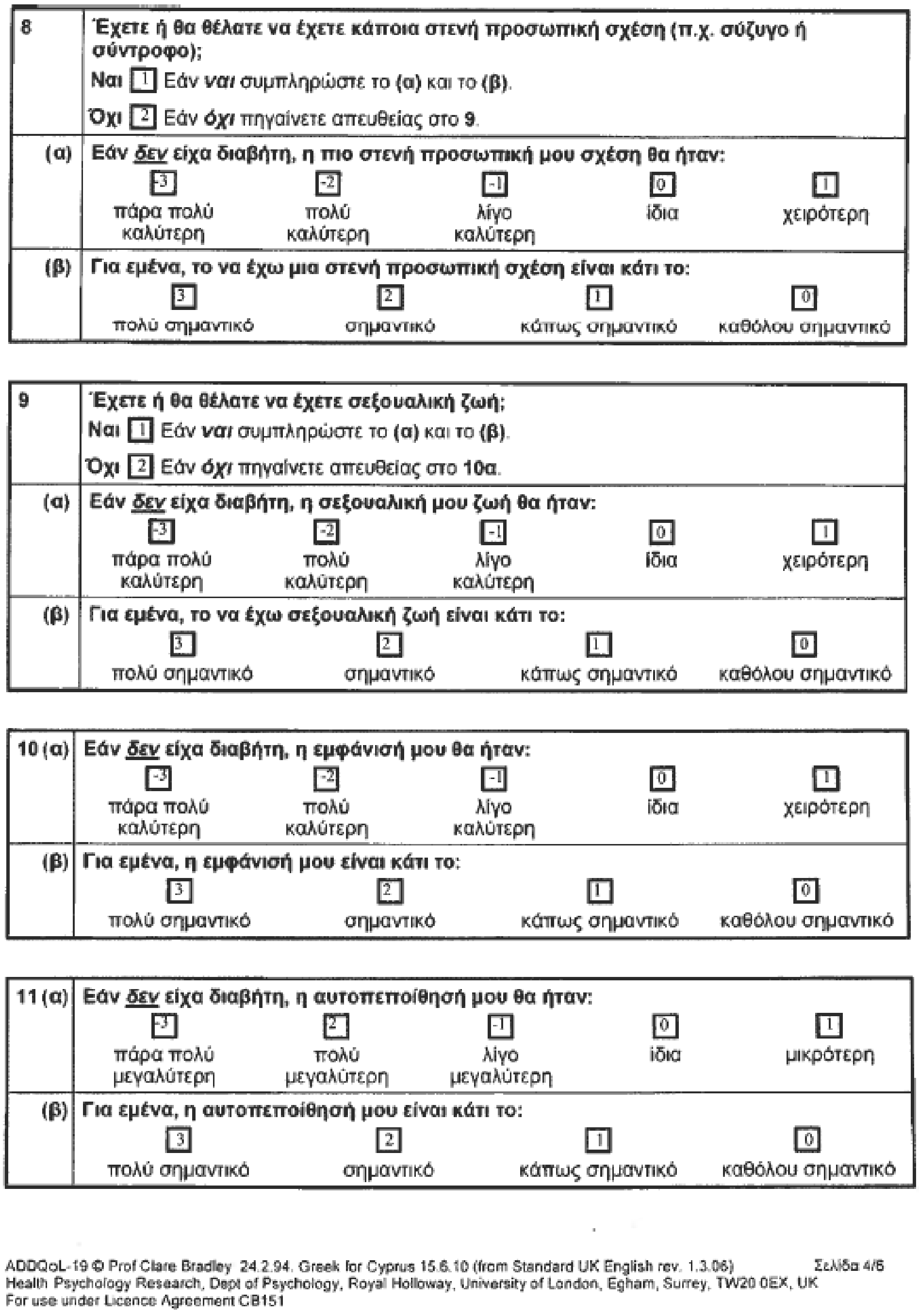
3	2	1	0
πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό

7 (α) **Εάν *δεν* είχα διαβήτη, οι φιλίες μου και η κοινωνική ζωή μου θα ήταν:**

-3	-2	-1	0	1
πάρα πολύ καλύτερες	πολύ καλύτερες	λίγο καλύτερες	ίδιες	χειρότερες

(β) **Για εμένα, οι φιλίες μου και η κοινωνική ζωή μου είναι κάτι το:**

3	2	1	0
πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό



8 **Έχετε ή θα θέλατε να έχετε κάποια στενή προσωπική σχέση (π.χ. σύζυγο ή σύντροφο);**

Ναι 1 Εάν ***ναι*** συμπληρώστε το **(α)** και το **(β)**.

Όχι 2 Εάν ***όχι*** πηγαίνετε απευθείας στο **9**.

(α) **Εάν <u>δεν</u> είχα διαβήτη, η πιο στενή προσωπική μου σχέση θα ήταν:**

-3	-2	-1	0	1
πάρα πολύ καλύτερη	πολύ καλύτερη	λίγο καλύτερη	ίδια	χειρότερη

(β) **Για εμένα, το να έχω μια στενή προσωπική σχέση είναι κάτι το:**

3	2	1	0
πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό

9 **Έχετε ή θα θέλατε να έχετε σεξουαλική ζωή;**

Ναι 1 Εάν ***ναι*** συμπληρώστε το **(α)** και το **(β)**.

Όχι 2 Εάν ***όχι*** πηγαίνετε απευθείας στο **10α**.

(α) **Εάν <u>δεν</u> είχα διαβήτη, η σεξουαλική μου ζωή θα ήταν:**

-3	-2	-1	0	1
πάρα πολύ καλύτερη	πολύ καλύτερη	λίγο καλύτερη	ίδια	χειρότερη

(β) **Για εμένα, το να έχω σεξουαλική ζωή είναι κάτι το:**

3	2	1	0
πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό

10 (α) **Εάν <u>δεν</u> είχα διαβήτη, η εμφάνισή μου θα ήταν:**

-3	-2	-1	0	1
πάρα πολύ καλύτερη	πολύ καλύτερη	λίγο καλύτερη	ίδια	χειρότερη

(β) **Για εμένα, η εμφάνισή μου είναι κάτι το:**

3	2	1	0
πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό

11 (α) **Εάν <u>δεν</u> είχα διαβήτη, η αυτοπεποίθησή μου θα ήταν:**

-3	-2	-1	0	1
πάρα πολύ μεγαλύτερη	πολύ μεγαλύτερη	λίγο μεγαλύτερη	ίδια	μικρότερη

(β) **Για εμένα, η αυτοπεποίθησή μου είναι κάτι το:**

3	2	1	0
πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό

12 (α) **Εάν _δεν_ είχα διαβήτη, η όρεξη / διάθεσή μου για να κάνω κάτι θα ήταν:**

☐ -3	☐ -2	☐ -1	☐ 0	☐ 1
πάρα πολύ καλύτερη	πολύ καλύτερη	λίγο καλύτερη	ίδια	χειρότερη

(β) **Για εμένα, το να έχω όρεξη / διάθεση να κάνω κάτι είναι κάτι το:**

☐ 3	☐ 2	☐ 1	☐ 0
πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό

13 (α) **Εάν _δεν_ είχα διαβήτη, ο τρόπος με τον οποίο οι άνθρωποι θα συμπεριφέρονταν απέναντί μου θα ήταν:**

☐ -3	☐ -2	☐ -1	☐ 0	☐ 1
πάρα πολύ καλύτερος	πολύ καλύτερος	λίγο καλύτερος	ίδιος	χειρότερος

(β) **Ο τρόπος με τον οποίο οι άνθρωποι συμπεριφέρονται απέναντί μου είναι κάτι το:**

☐ 3	☐ 2	☐ 1	☐ 0
πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό

14 (α) **Εάν _δεν_ είχα διαβήτη, τα συναισθήματά μου για το μέλλον (π.χ. ανησυχίες, ελπίδες) θα ήταν:**

☐ -3	☐ -2	☐ -1	☐ 0	☐ 1
πάρα πολύ καλύτερα	πολύ καλύτερα	λίγο καλύτερα	ίδια	χειρότερα

(β) **Για εμένα, τα συναισθήματά μου για το μέλλον είναι κάτι το:**

☐ 3	☐ 2	☐ 1	☐ 0
πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό

15 (α) **Εάν _δεν_ είχα διαβήτη, η οικονομική μου κατάσταση θα ήταν:**

☐ -3	☐ -2	☐ -1	☐ 0	☐ 1
πάρα πολύ καλύτερη	πολύ καλύτερη	λίγο καλύτερη	ίδια	χειρότερη

(β) **Για εμένα, η οικονομική μου κατάσταση είναι κάτι το:**

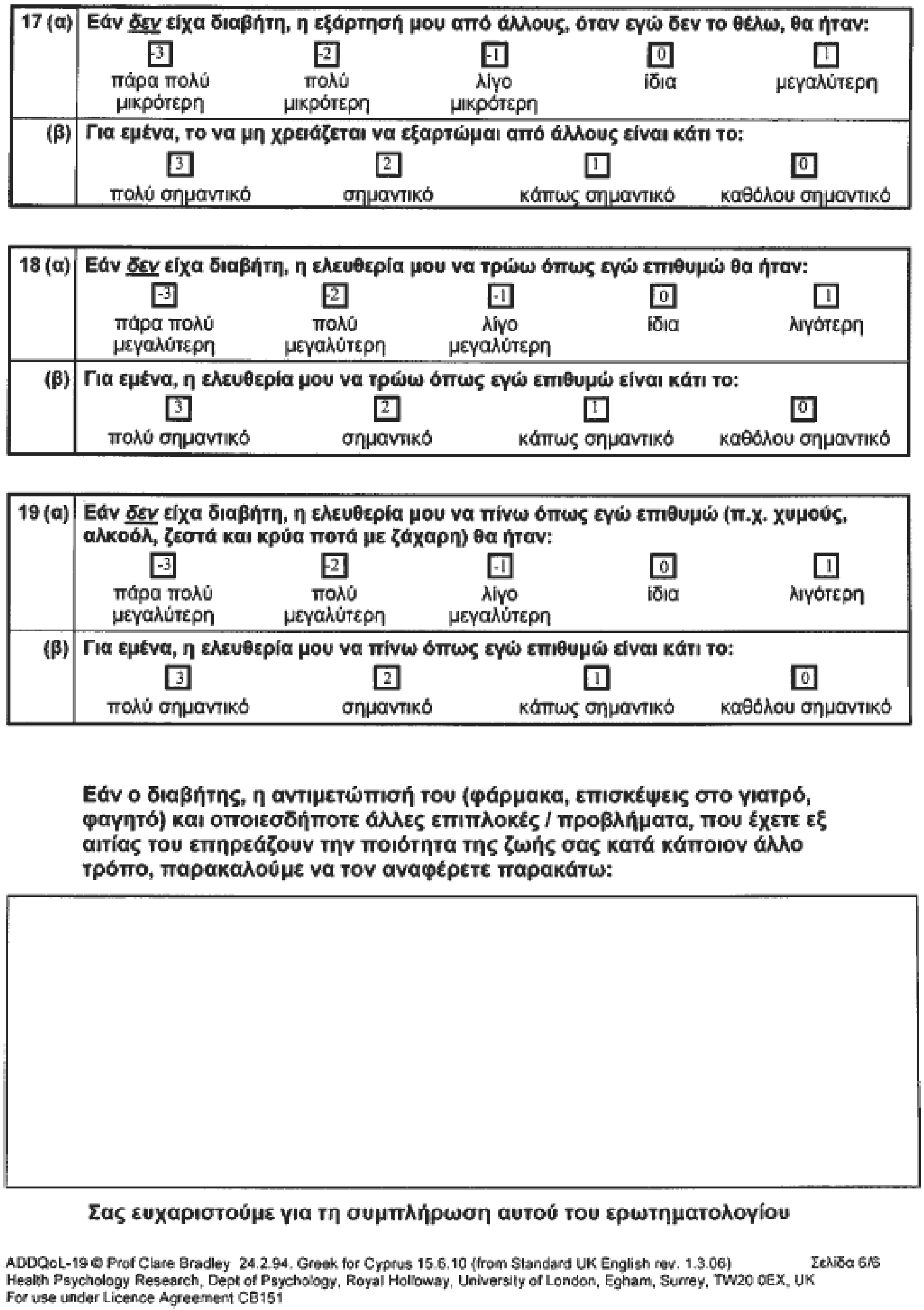
☐ 3	☐ 2	☐ 1	☐ 0
πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό

16 (α) **Εάν _δεν_ είχα διαβήτη, οι συνθήκες της καθημερινής μου ζωής θα ήταν:**

☐ -3	☐ -2	☐ -1	☐ 0	☐ 1
πάρα πολύ καλύτερες	πολύ καλύτερες	λίγο καλύτερες	ίδιες	χειρότερες

(β) **Για εμένα, οι συνθήκες της καθημερινής μου ζωής είναι κάτι το:**

☐ 3	☐ 2	☐ 1	☐ 0
πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό



17 (α)	**Εάν *δεν* είχα διαβήτη, η εξάρτησή μου από άλλους, όταν εγώ δεν το θέλω, θα ήταν:**				
	-3	-2	-1	0	1
	πάρα πολύ μικρότερη	πολύ μικρότερη	λίγο μικρότερη	ίδια	μεγαλύτερη
(β)	**Για εμένα, το να μη χρειάζεται να εξαρτώμαι από άλλους είναι κάτι το:**				
	3	2	1	0	
	πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό	

18 (α)	**Εάν *δεν* είχα διαβήτη, η ελευθερία μου να τρώω όπως εγώ επιθυμώ θα ήταν:**				
	-3	-2	-1	0	1
	πάρα πολύ μεγαλύτερη	πολύ μεγαλύτερη	λίγο μεγαλύτερη	ίδια	λιγότερη
(β)	**Για εμένα, η ελευθερία μου να τρώω όπως εγώ επιθυμώ είναι κάτι το:**				
	3	2	1	0	
	πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό	

19 (α)	**Εάν *δεν* είχα διαβήτη, η ελευθερία μου να πίνω όπως εγώ επιθυμώ (π.χ. χυμούς, αλκοόλ, ζεστά και κρύα ποτά με ζάχαρη) θα ήταν:**				
	-3	-2	-1	0	1
	πάρα πολύ μεγαλύτερη	πολύ μεγαλύτερη	λίγο μεγαλύτερη	ίδια	λιγότερη
(β)	**Για εμένα, η ελευθερία μου να πίνω όπως εγώ επιθυμώ είναι κάτι το:**				
	3	2	1	0	
	πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό	

Εάν ο διαβήτης, η αντιμετώπισή του (φάρμακα, επισκέψεις στο γιατρό, φαγητό) και οποιεσδήποτε άλλες επιπλοκές / προβλήματα, που έχετε εξ αιτίας του επηρεάζουν την ποιότητα της ζωής σας κατά κάποιον άλλο τρόπο, παρακαλούμε να τον αναφέρετε παρακάτω:

Σας ευχαριστούμε για τη συμπλήρωση αυτού του ερωτηματολογίου

APPENDIX XXI

Έντυπο καταγραφής οξέων συμβάντων

Όνομα ασθενούς………..

Επανεισαγωγή

1. **Αιτία επανεισαγωγής…………………………………………………………………………………………………….**
2. **Ημερομηνία επανεισαγωγής………………/…………/……………………………………………………**
3. **Ημερομηνία εξιτηρίου……………/…………/……………………………………………………………………**

Θάνατος

1. **Αιτία θανάτου………………………………………………………………………… ……………………………**

2. **Ημερομηνία θανάτου………../………../……………………………………………………… ………………….**

APPENDIX XXII

ΙΣΤΟΡΙΚΟ

Νοσοκομείο .... Αρ. Αρχείου............................

Θάλαμος....................................... Θεράπων Γιατρός....................................

Ημερομηνία .... Ημερομηνία Εισαγωγής ....

Αρχική Διάγνωση .... Διάγνωση κατά το εξιτήριο.......................

ΔΗΜΟΓΡΑΦΙΚΑ ΣΤΟΙΧΕΙΑ

ΠΡΟΣΩΠΙΚΑ ΣΤΟΙΧΕΙΑ

Όνομα ασθενούς: ……………............ Επίθετο: ………………………………………….

Αριθμός Ταυτότητας: ……………………… Φύλο: Άρρεν ☐ Θήλυ ☐

Ημ. Γέννησης: ..../........./......................

Εθνικότητα: .... Ιθαγένεια: …………………………………………..

Οικογενειακή κατάσταση ☐ Παντρεμένος/η ☐ Διαζευγμένος/η

☐ Χήρος/α ☐ Ελεύθερος/η

Επάγγελμα / Ιδιότητα: ....

Εκπαίδευση: ☐ Δημοτικό ☐ Λύκειο ☐ Ανώτερη ☐ Ανωτάτη ☐ Μεταπτ/κή

Παρούσα κατάσταση: ☐ Εργοδοτούμενος ☐ Άνεργος ☐ Συνταξιούχος ☐ Με αναπηρία

Μένει: ☐ Με την οικογένεια

☐ Στο σπίτι μόνος/η με βοήθεια από την οικογένεια

☐ Στο σπίτι μόνος/η με οικιακή βοηθό

☐ Στο σπίτι μόνος/η με βοήθεια από την κοινωνική πρόνοια

☐ Σε οίκο ευγηρίας

☐ Αλλού: Διευκρινίστε ....

Προσωπικός Γιατρός: ....

Τηλέφωνο προσωπικού γιατρού: ....

ΣΤΟΙΧΕΙΑ ΕΠΙΚΟΙΝΩΝΙΑΣ

Διεύθυνση κατοικίας:...

....

Τηλέφωνο: 1. ………………………………. 2. …………………………………………......

Πλησιέστερος συγγενής / φροντιστής : ....

Συγγένεια / Σχέση: ....

Τηλέφωνο πλησιέστερου συγγενή: ……………………………..............................

ΣΤΟΙΧΕΙΑ ΕΙΣΑΓΩΓΗΣ

Ώρα εισαγωγής: ☐ ΠΜ ☐ ΜΜ

Τρόπος Προσέλευσης: ☐ Απευθείας προσέλευση στο Τμήμα Πρώτων Βοηθειών
☐ Προγραμματισμένη εισαγωγή
☐ Παραπομπή από προσωπικό γιατρό
☐ Κλήση Ασθενοφόρου

Με συνοδεία: ☐ ΝΑΙ ☐ ΟΧΙ

Κύριο ενόχλημα κατά την εισαγωγή: ....

Συμπτώματα / Σημεία κατά την εισαγωγή:

☐ Δύσπνοια
☐ Ορθόπνοια
☐ Λήθαργος
☐ Περικάρδιο άλγος / Στηθάγχη
☐ Αίσθημα παλμών
☐ Κόπωση
☐ Οίδημα
☐ Συριγμός
☐ Υπέρταση ή Υπόταση
☐ Άλλα: ....
……………………………………………….

ΙΑΤΡΙΚΟ ΙΣΤΟΡΙΚΟ

ΠΑΛΑΙΟΤΕΡΟ ΙΣΤΟΡΙΚΟ

Αλλεργίες : ……………………………………………………………………………………………

Προηγούμενες εισαγωγές στο νοσοκομείο: ☐ ΝΑΙ ☐ ΟΧΙ

Αν ναι, αιτία:
1.………………………………………………………………………………………………………
2.………………………………………………………………………………………………………
3.………………………………………………………………………………………………………

Επεμβάσεις:

1.………………………………………………………………………………………………………

2.………………………………………………………………………………………………………

3.………………………………………………………………………………………………………

4.……………………………………………………………………………………………………

Παλαιότερα νοσήματα:
……
……
……

Χρόνια συνοδά νοσήματα:

Ρευματική νόσος: ☐ ΝΑΙ ☐ ΟΧΙ

Χρόνια νεφρική ανεπάρκεια: ☐ ΝΑΙ ☐ ΟΧΙ

Χρόνια αποφρακτική πνευμονοπάθεια: ☐ ΝΑΙ ☐ ΟΧΙ

Άσθμα: ☐ ΝΑΙ ☐ ΟΧΙ

Αγγειακό Εγκεφαλικό Επεισόδιο: ☐ ΝΑΙ ☐ ΟΧΙ

Άλλα:……………………………….

………………………………..

……………………………….

Φυσική Κατάσταση:

Άθληση / Άσκηση: ☐ ΝΑΙ ☐ ΟΧΙ

Χρήση ουσιών: ☐ ΝΑΙ ☐ ΟΧΙ

ΚΑΡΔΙΟΛΟΓΙΚΟ ΙΣΤΟΡΙΚΟ

Οικογενειακό ιστορικό: ☐ ΟΧΙ ☐ ΝΑΙ

Αριθμός Ά Βαθμού Συγγενών: ....

Παράγοντες κινδύνου:

☐ Υπέρταση ☐ Κατάχρηση αλκοόλ ☐ Παχυσαρκία

☐ Διαβήτης ☐ Υπερλιπιδαιμία ☐ Καρδιοτοξικά φάρμακα

Κάπνισμα : ☐ ΟΧΙ ☐ ΝΑΙ ☐ Παθητικό κάπνισμα

☐ Κοινωνικό κάπνισμα

☐ Τακτικός καπνιστής

Ενεργός καπνιστής ; ☐ ΝΑΙ ☐ ΟΧΙ

Συνολικά έτη καπνίσματος: 1-5 έτη 6-10 έτη 11-20 έτη πάνω από 20

Υποκείμενη Νόσος:

☐ Στεφανιαία Νόσος
☐ Βαλβιδοπάθεια
☐ Άλλο ....
……………………………….
……………………………….

☐ Αρρυθμίες
☐ Υπερτασική μυοκαρδιοπάθεια

☐ Μυοκαρδιοπάθεια
☐ Χρόνια κολπική μαρμαρυγή

Φαρμακευτική αγωγή στο σπίτι πριν την εισαγωγή:

1. .... Δόση .... Συχνότητα: OD BD TDS QID PRN
2. .... Δόση .... Συχνότητα: OD BD TDS QID PRN
3. .... Δόση .... Συχνότητα: OD BD TDS QID PRN
4. .... Δόση .... Συχνότητα: OD BD TDS QID PRN
5. .... Δόση .... Συχνότητα: OD BD TDS QID PRN
6. .... Δόση .... Συχνότητα: OD BD TDS QID PRN
7. .... Δόση .... Συχνότητα: OD BD TDS QID PRN
8. .... Δόση .... Συχνότητα: OD BD TDS QID PRN
9. .... Δόση .... Συχνότητα: OD BD TDS QID PRN
10........................... Δόση .... Συχνότητα: OD BD TDS QID PRN

Αγγειογραφία:		☐ ΟΧΙ	
		☐ ΝΑΙ	Ημερομ. : …………
			☐ Με ευρήματα
Ιστορικό εμφράγματος του μυοκαρδίου:		☐ ΟΧΙ	
Θρομβόλυση			
☐ ΟΧΙ		☐ ΝΑΙ	Ημερομ. : …………
☐ ΝΑΙ			
Αγγειοπλαστική (Μπαλονάκι):		☐ ΟΧΙ	
		☐ ΝΑΙ	Ημερομ. : …………
Αορτοστεφανιαία Παράκαμψη (By Pass):		☐ ΟΧΙ	
		☐ ΝΑΙ	Ημερομ. : …………
Εμφυτευμένες συσκευές (implantable devices)			
	Μόνιμος Βηματοδότης:	☐ ΟΧΙ	
		☐ ΝΑΙ	Ημερομ. : …………
	Εμφυτευμένος απινιδωτής (ICD)	☐ ΟΧΙ	
		☐ ΝΑΙ	Ημερομ. : …………
	Συσκευή συγχρονισμένης βηματοδότησης (CRT)	☐ ΟΧΙ	
		☐ ΝΑΙ	Ημερομ. : …………

Συσκευή υποβοήθησης αριστερής κοιλίας (LVAD) ☐ ΟΧΙ
☐ ΝΑΙ Ημερομ. : …………

Προσθετικές Βαλβίδες: ☐ ΟΧΙ
☐ ΝΑΙ Ημερομ. : …………

Ηλεκτροφυσιολογική μελέτη: ☐ ΟΧΙ
☐ ΝΑΙ Ημερομ. : …………

Νοσηλεία στη ΜΕΘ: ☐ ΟΧΙ
☐ ΝΑΙ Ημερομ. : …………
Αιτία: ....
Ήμερες νοσηλείας: ....

ΚΑΡΠΑ: ☐ ΟΧΙ
☐ ΝΑΙ Ημερομ. : ....

Ανάταξη από εμφυτευμένη συσκευή: ☐ ΟΧΙ
☐ ΝΑΙ Ημερομ. : ....

ΚΑΤΑ ΤΗ ΝΟΣΗΛΕΙΑ

Διαγνωστικές Εξετάσεις:

☐ Υπερηχοκαρδιογράφημα Κλάσμα εξώθησης (LV Ejection Fraction) ……… %

☐ Συστολική Δυσλειτουργία αρ. κοιλίας

☐ Υπερτροφία αριστερής κοιλίας

☐ Στένωση μιτροειδούς

☐ Στένωση αορτικής βαλβίδας

☐ Βαλβιδική παλινδρόμηση ☐ αορτική

☐ μιτροειδική

☐ πνευμονική

☐ τριγλωχινική

☐ Ακτινογραφία θώρακα: ☐ Χωρίς ευρήματα ☐ Πνευμονικό Οίδημα

☐ Πλευριτική συλλογή ☐ Πνευμονική λοίμωξη

☐ Ατελεκτασία ☐ Άλλα παθολογικά ευρήματα

☐ ΗΚΓ: Ρυθμός ☐ Φλεβοκομβικός ☐ Κολπική Μαρμαρυγή

☐ Βηματοδοτούμενος ☐ Άλλος ………………………………………..

Παλαιό ΕΜ ☐ ΝΑΙ ☐ ΟΧΙ

☐ BNP τιμή ………………………………………

☐ NT-pro BNP τιμή ……………………………………

☐ Απεικόνιση με ραδιονουκλίδια (σπινθηρογράφημα)

Ευρήματα ………………………………………

☐ Καθετηριασμός Ευρήματα………………………………..

☐ Μαγνητική τομογραφία (MRI) / Αξονική τομογραφία (CT)

☐ Αιματολογικός – Βιοχημικός έλεγχος

Τιμές της πιο πρόσφατης ανάλυσης Ημερομηνία ....

Na	…………	mmol/l	Glucose	…………	mg/dl
K	…………	mmol/l	Hb	…………	gr/dl
Ca	…………	mmol/l	WBC	…………	x 10 ^{9}/l
Cl	…………	mmol/l	PLT	…………	x 10 ^{9}/l
Mg	…………	mmol/l	NaHCO3	…………	mmol/l
Urea	…………	mmol/l	Creatinine	…………	mmol/l

HbA1C………..%

ΣΤΟΙΧΕΙΑ ΚΑΤΑ ΤΟ ΕΞΙΤΗΡΙΟ

Ημερομηνία εξιτηρίου:…………………………………………………

Ταξινόμηση κατά NYHA ☐ I ☐ II ☐ III ☐ IV

Βάρος: ……………………………… Ύψος: .... ΔΜΣ: ....

Εξιτήριο: ☐ Στο σπίτι

☐ Σε κλινική αποκατάστασης

☐ Σε οίκο ευγηρίας

☐ Σε συγγενείς

☐ Αλλού ....

Συμπτώματα / Σημεία κατά το εξιτήριο:

☐ Δύσπνοια

☐ Ορθόπνοια

☐ Προκάρδιο άλγος/Στηθάγχη

☐ Αίσθημα παλμών

☐ Ακροαστικά πνευμόνων

☐ Ανορεξία

☐ Κόπωση

☐ Αναιμία

☐ Ζάλη

☐ Ασκίτης

☐ Συριγμός

☐ Άλλα: ....

☐ Οίδημα: ☐ Σφυρών ☐ Γαστροκνημίας ☐ Μηρών ☐ Κοιλιακή χώρα

ΑΠ κατά το εξιτήριο: ....

Καρδιακός ρυθμός κατά το εξιτήριο:

Συχνότητα ....

☐ ΦΚ

☐ Κολπική Μαρμαρυγή

☐ Βηματοδοτούμενος

☐ Έκτακτες συστολές

☐ Άλλο ....

Φαρμακευτική Αγωγή κατά το εξιτήριο

☐ Διουρητικό Αγκύλης	Σκεύασμα	………………………..	Δόση	…………….
☐ Διγοξίνη	Σκεύασμα	………………………..	Δόση	…………….
☐ Σπιρονολακτόνη	Σκεύασμα	………………………..	Δόση	…………….
☐ Β-αποκλειστές	Σκεύασμα	………………………..	Δόση	…………….
☐ Αναστολείς Διαύλων Ca++	Σκεύασμα	………………………..	Δόση	…………….
☐ ΑΜΕΑ / ΑΤ ΙΙ	Σκεύασμα	………………………..	Δόση	…………….
☐ Θειαζίδη / Μετολαζονη	Σκεύασμα	………………………..	Δόση	…………….
☐ Νιτρώδη	Σκεύασμα	………………………..	Δόση	…………….
☐ Σπρέι Νιτρογλυκερίνης	Σκεύασμα	………………………..	Δόση	…………….
☐ Ασπιρίνη	Σκεύασμα	………………………..	Δόση	…………….
☐ Κουμαρινικά	Σκεύασμα	………………………..	Δόση	…………….
☐ Στατίνες	Σκεύασμα	………………………..	Δόση	…………….
Άλλα: 1…….Ινσουλίνη……………….….	Σκεύασμα	………………………..	Δόση	…………….

2……..Αντιδιαβητικά δισκία…………………..	Σκεύασμα	………………………..	Δόση	………….
3………………………….	Σκεύασμα	………………………..	Δόση	………….
4………………………….	Σκεύασμα	………………………..	Δόση	………….
5………………………….	Σκεύασμα	………………………..	Δόση	………….
6………………………….	Σκεύασμα	………………………..	Δόση	………….

ΕΚΠΑΙΔΕΥΣΗ:

Εκπαίδευση κατα το εξιτήριο: ☐ ΝΑΙ ☐ ΟΧΙ

Δόθηκε έντυπο εκπαιδευτικό υλικό: ☐ ΝΑΙ ☐ ΟΧΙ

Εκπαίδευση της οικογένειας: ☐ ΝΑΙ ☐ ΟΧΙ

APPENDIX XXIII

The clinical case of the patient diagnosed with cardiac amyloidosis.

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Case Report

Heart Failure (HF) Nurses and Allied Professionals Specialists Contribute to Differential Diagnosis of Patients with HF and Comorbidities

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Abstract

Patient presentation: A 76 years old male patient with Heart Failure (HF) enrolled in the nurse-led management program 'Support Heart' is presented in the current clinical case. Even though he was well educated and supported through the program, he had several deterioration and re-hospitalizations, during a few months period. The symptoms remained after his discharge and specialist nurses of the program advised him to visit a cardiologist specialist on HF and other specialists as well who diagnosed amyloidosis.
Initial work-up: The patient was introduced to the management program 'Support Heart' after he was diagnosed with HF with preserved Ejection Fraction (HFpEF). 'Support Heart' program includes specialist nurses and physiotherapists on HF who collaborate with cardiologists; and provide monthly follow-up meetings in which the patients are educated, ask questions, do exercise, walking etc. During the pandemic and the lockdowns (a few months period), the patient was admitted three times within the cardiology ward with dyspnea NYHA III and swelled legs with ulcers. The first meeting of the program after the lockdown was only a few days after discharge. HF nurses during his assessment found that the symptoms were not better and undertook a more detailed medical history when they found out that his brother died from a liver disease. The family history with the unknown disease and the continuing symptoms were the reasons that nurses referred the patient to a HF cardiologist specialist. The cardiologist suspected amyloidosis and asked for further evaluation tests.
Diagnosis and management: The scintigraphy and hematological tests suggested transthyretin amyloidosis. His therapy then was optimized and upgraded with disease specific treatment (tafamidis) for amyloidosis and the clinical presentation of the patient was improved. His NYHA stage became II and the ulcers were much better. The nurses of the 'Support Heart' program were informed by the cardiologist about the new therapy and the necessary follow-up treatment.
Follow-up: Amyloidosis is an increasingly recognized but too often underestimated cause of HF. It is often underdiagnosed due to the lack of clinical manifestations. The new possibilities of imaging and tests along with a careful clinical assessment and medical history provide the opportunity for early diagnosis, optimization of the therapy and improved clinical outcomes. The HF nurses of the 'Support Heart' program explained to the patient about cardiac amyloidosis and how it changes his treatment and follow-up of the multi-disciplinary team. Then, they made together with the physiotherapist of the program a new program of physical activity since his physical condition along with his mental condition were improved.
Conclusion-Learning points: Specialist nurses and physiotherapists in HF and supportive nurse-led management programs may contribute to differential diagnosis of patients with HF and comorbidities and improve the outcomes of the patient and the coordination of health professional specialists. Patients with HF who are mostly older people with comorbidities need continuing support, evaluation and optimization of therapy.

Keywords: ATTR Amyloidisis; Transthyretin (TTR) Cardiac Amyloidisis; Tafamidis

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Introduction

Amyloidosis is a heterogeneous family of diseases induced by deposition of misfolded proteins in the form of amyloid fibrils within the extracellular space of various organs. Amyloid deposits are histologically identifiable by characteristic apple-green birefringence when stained with Congo-Red dye and examined under cross-polarized light.

As confirmation of the amyloid fibril type is essential to direct clinical management and disease-modifying therapy, in such inconclusive cases, the use of immunogold electron microscopy and mass spectrometry confer the greatest sensitivity and specificity for amyloid typing [1,2]. Major advances in imaging such as scintigraphy with bone tracer and cardiac magnetic resonance (CMR) have heralded a non-invasive approach to diagnosis of ATTR-CA, which now may be achieved without recourse to histological demonstration of amyloid in ≈70% of the cases [3].

Transthyretin (TTR) amyloidosis (ATTR amyloidosis), is an underdiagnosed, life-threatening disease characterized by progressive deposition of misfolded or cleaved TTR protein in organs [1,4]. Disease occurs when aggregation of amyloid fibrils in the extracellular space disrupts the structure, integrity and function of the affected tissue. In clinical practice, ATTRwt amyloidosis manifests as a predominant cardiomyopathy [transthyretin cardiac amyloidosis (ATTR-CA)], while ATTRv amyloidosis is typically associated with Polyneuropathy (ATTR-PN) as well as cardiomyopathy [5].

Amyloid deposition in the heart leads to expansion of the extracellular space with associated disruption in myocardial architecture, systolic and diastolic function [6]. The increase in myocardial mass determines a progressively smaller ventricular cavity size, resulting in fixed end-diastolic volume. ATTR-CA is slowly progressive and clinically well tolerated until marked ventricular wall thickening, severe diastolic dysfunction and conduction system disease have occurred [1,4].

Case Report

A 76 years old male patient with HF who was enrolled to the nurse led management program 'Support Heart' with reduced ejection fraction admitted for third time in the cardiology ward with dyspnea NYHA III and swelled legs with ulcer. The patient was admitted another two times with deterioration of symptoms during the pandemic and lockdown. He was educated about the HF and was supported for self-management using several educational methods during monthly meetings and telephone follow-up. After the therapy with diuretics and bronchodilators, the patient was discharged, but the symptoms did not improve. It was considered as fatigue due to the existing disease. Moreover, the patient complained that he could not use the walking aid because his wrists were aching. His arterial Blood Pressure (BP) was also lower than usual.

He had a normal BMI but he can't walk without walking aid. At the first meeting of the program after the lockdown, he was only a few days after the last discharge. HF nurses during his assessment found that the symptoms remained. His BP remained lower than usual and his medication had to be modified. undertook a more detailed medical history when they found out that his brother died from a liver disease. The family history with the unknown disease and the continuing symptoms were the reasons that nurses referred the patient to a HF cardiologist specialist. The cardiologist suspected amyloidosis and asked for further evaluation tests.

Individual history includes coronary disease-multiple PCI, chronic atrial fibrillation, hypertension, and diabetes mellitus. Medication at the period of readmissions included: carvedilol, ezetimibe, metformin, rivaroxaban, amlodipine/valsartan, rosuvastatin, allopurinol, alfuzocin. FBC and Biochemical tests were normal. ECG showed sinus rhythm with first-degree atrioventricular block **(Figure 1)**.

ECHO showed preserved ejection fraction 55%, normal dimension with severe degree of centralized left ventricular wall hypertrophy (LVEDD=42mm, IVS=16mm PW=16mm) **(Figure 2)**.
An osteomedelic biopsy was performed to rule systematic amyloidosis out. It was negative. The patient was referred for heart scintigraphy. Results showed moderately increased myocardial uptake of radiopharmaceuticals (Grade =2) and compatible finding with ATTR amyloidosis **(Figure 3)**.

The therapy then was optimized and upgraded with disease specific treatment (tafamidis) for amyloidosis. Due to the severity and the long term of the disease the improvement was slow. One year later the patient was able to walk without walking aid, his HF symptoms were in remission and he had a marked improvement on his health related -quality of life.

Discussion

Cardiac amyloidosis is frequently misdiagnosed, so the patients in many cases don't have the opportunity for appropriate optimization of the treatment management of the disease [6]. The relevance of the present clinical case was based on the ESC Clinical Guidelines for the diagnosis of Cardiac Amyloidosis [4]. The patient of the clinical case had left ventricular wall thickness ≥ 12mm (=16 mm) from the echocardiogram and four "red flugs" that were the following: 1. Diagnosed patient with Heart Failure (HFpEF = 55%) older than 65 years old, 2. Hypotensive patient and previously was hypertensive 3. Ppatient with bilateral carpal tunnel syndrome and 4. Possible family history.

Early diagnosis and clinical suspicion

Early diagnosis of amyloidosis by using non-invasive testing (first and foremost scintiscan with bone markers) should always be guided by clinical suspicion but should also be supported by a multidisciplinary approach with the aim to improve the prognosis of the condition [6]. In the present clinical case, the patient was involved in a nurse-led supporting care program for the management of HF in Cyprus named "Support Heart". During the monthly meetings, the nurses of the program observed that during patients' assessment the symptoms remained after the treatment he received during and after the three times of his hospitalizations. Nurses undertook again a detailed medical and family history.

The patient referred that his brother died from an unspecified liver disease and himself had bilateral carpal tunnel syndrome the last months. The carpal tunnel syndrome earns special attention and especially if appears bilateral. In male patients this is highly suggestive of ATTR (up to 50%) and in the studies, it seems to lead up to the cardiac involvement of 5– 7years [6,7].

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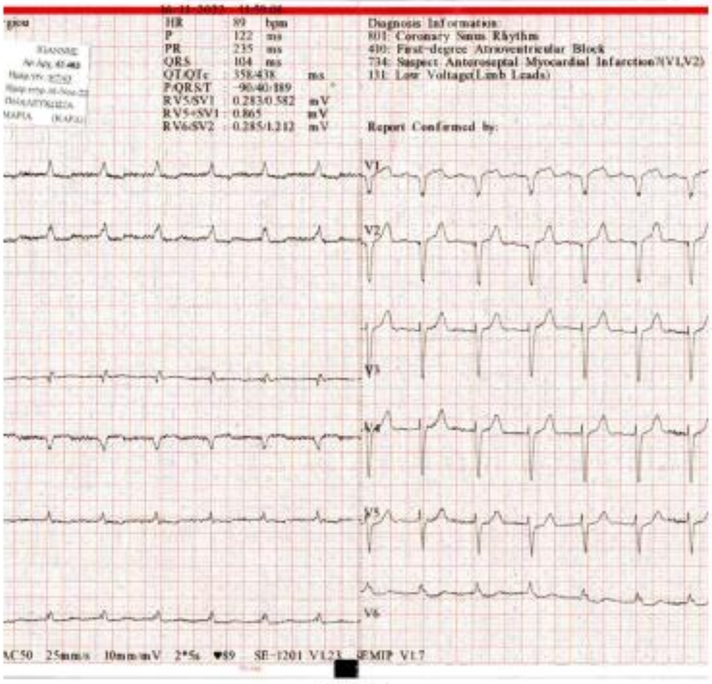

HR	89	bpm
P	122	ms
PR	235	ms
QRS	104	ms
QT/QTc	358/438	ms
P/QRS/T	-90/40/189	°
RV5/SV1	0.283/0.582	mV
RV5+SV1	0.865	mV
RV6/SV2	0.285/1.212	mV

Diagnosis Information:
801: Coronary Sinus Rhythm
409: First-degree Atrioventricular Block
734: Suspect Anteroseptal Myocardial Infarction?(V1,V2)
131: Low Voltage(Limb Leads)

Report Confirmed by:

AC50 25mm/s 10mm/mV 2*5s ♥89 SE-1201 V1.23 SEMIP V1.7

Figure 1

Figure 2

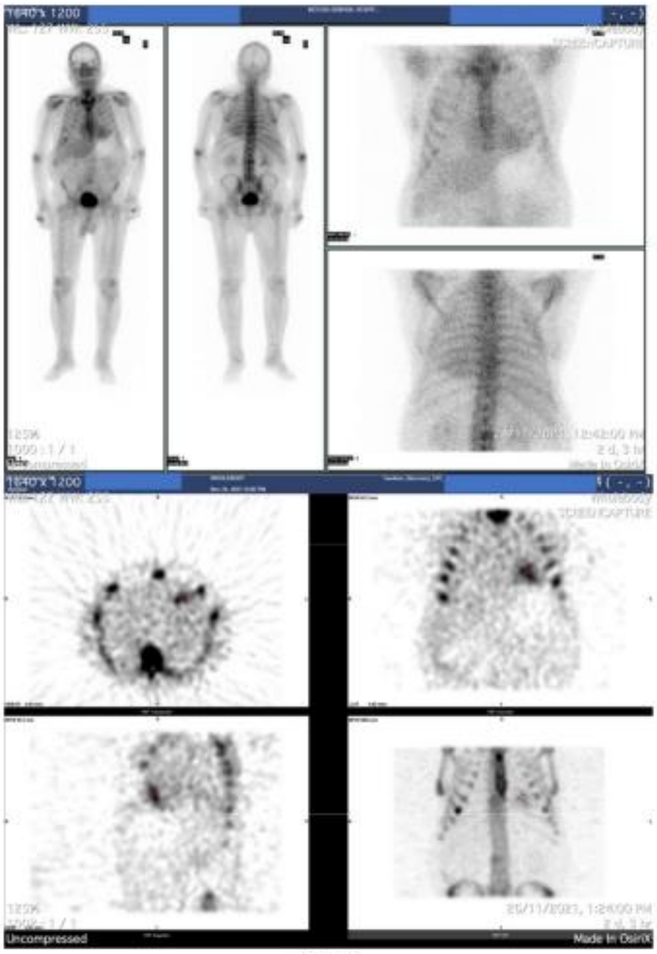

Figure 3

The nurses of the "Support Heart" team referred the patient to a HF cardiologist specialist who also suspected amyloidosis and asked for further evaluation tests. Therefore, the proper assessment and evaluation by the nurses of the "Support Heart" program leaded to the early and proper diagnosis for cardiac amyloidosis. The role of the multidisciplinary team is fundamental for the early diagnosis of cardiac amyloidosis.

The collaboration of HF nurses and cardiologists' specialists, is essential and is important that nurses must also be aware and have the clinical suspicion of the symptoms of cardiac amyloidosis. The aim is to contribute to early diagnosis and treatment, since patients with early diagnosis and care, have better outcomes and health related quality of life [8,9].

Conclusion

Cardiac amyloidosis is a condition that is fatal and progressive. [9]. A late diagnosis significantly affects the prognosis of the patients and the possibility of undertaking the proper therapies, so they may lack the possibility to heal or slowing the progression of the disease, despite the fact that new medications are used.

Several "red flags" have been identified and may raise suspicion for the presence of the disease [3,10]. Therefore, if there is the appropriate knowledge and assessment by members of the multidisciplinary heath care team, such as HF nurses, the identification of the complex picture of signs and symptoms related to amyloidosis, makes the early diagnosis appropriate therapeutic procedure possible leading to improved outcomes.

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