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**The Health Promoting Conversations intervention for families with a critically ill  
relative: a pilot RCT**

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1 **Word count:**

2 **Introduction**

3 Viewing the family as a unit (patient and family members together) of research and care is  
4 still very rare in Swedish health care. Therefore, there is a lack of quantitative, evidence-  
5 based, family-centred interventions, such as the use of health-promoting family  
6 conversations, as supportive nursing actions for families with a critically ill member. Family  
7 health conversations between nurses and families are of utmost importance to create a  
8 trusting caring relationship and enhance family health after intensive care (Benzien et al.  
9 2008).

10 Every year, millions of people worldwide are discharged from intensive care units (ICUs)  
11 after a critical illness and continue their rehabilitation in hospital wards and at home  
12 (Iwashyna, 2010). Many ICU survivors have prolonged impairments that affect their  
13 physical, cognitive, and mental health. Because of the physical and emotional stress  
14 experienced during their critical illness and ICU hospitalisation, up to 20% are at risk of  
15 developing post-traumatic stress disorder (PTSD) (Davydow et al., 2008). Among the  
16 patient's family members, the prevalence of PTSD may be even higher (up to 57%)  
17 (Beusekom et al., 2016). Along with PTSD, family members may also experience symptoms  
18 of depression and anxiety, a syndrome called post-intensive care syndrome (PICS family)  
19 (Jensen et al., 2015; van Beusekom et al., 2016). Other factors that increase the risk of PICS  
20 family include condition severity, patient age and sex, whether the patient is treated with a  
21 ventilator, the severity of the illness, and previous anxiety in the family (Jensen et al., 2015;  
22 van Beusekom et al., 2016, Köse et al. 2016). A recent study found that these symptoms in  
23 family members persisted 3 months after ICU discharge while they decreased in patients  
24 (Fumis 2015). PICS family, should therefore be assessed in the family members of patients  
25 who survive ICU treatment (Probst et al. 2016).

1 ICU patients' family members are prone to shame feelings, especially when having low  
2 levels of education and living with the patient (Koulouras et al. 2017). Family members face  
3 overwhelming and emotionally challenging situations, and their concerns and needs must be  
4 addressed (Linnarsson et al., 2010). The family is important in terms of patient recovery;  
5 accordingly, health professionals should address the family's contributions to recovery to  
6 help prevent or improve the patient's post-ICU symptoms (Ågård et al., 2015). There is little  
7 evidence from RCTs regarding family support, although some studies have looked at patient  
8 diaries to assess psychological recovery after critical illness and to assess the contributions of  
9 family members to recovery. Studies reported that post-traumatic stress symptoms were  
10 reduced in the family members of patients recovering from ICU treatment who received  
11 patient diaries (Ullman et al., 2015, Parker et al. 2015).

12 A review article reports on Patient, Family-Centred Care (PFCC), an internationally  
13 advocated as a way to improve patient care. Research into PFCC interventions is diverse;  
14 however, few researchers present a multi-dimensional approach incorporating a culture shift  
15 to enact PFCC throughout the ICU trajectory (Mitchell et al. 2016). The foundation of  
16 family-focused nursing theory is based on the Family Assessment and Intervention model  
17 (Wright & Leahey 2009) and the Illness Belief Model (Wright & Bell 2009, Wright, Watson  
18 & Bell 2002) developed at the Family Nursing Unit, Calgary University, Canada. The models  
19 are based on systems theory, cybernetics, communication theory, and change theory. The  
20 Swedish model for family-focused nursing, influenced by the Calgary models, was developed  
21 in Kalmar by Benzein et al (2008). The theoretical foundation was based on salutogenetic and  
22 constructivist approaches. A model for communication between nurses and families, known  
23 as the Health-Promoting Family Conversation model, was derived from these theories.  
24 Essential elements of this model include viewing the world as multiversity (Maturana 1988)  
25 and using reflection as a way to change beliefs (Anderson 2003). The relationship between

1 the nurse and family is non-hierarchical, where communication is built on partnership. Both  
2 the nurse and the family contribute with their resources and knowledge; thus, meetings are  
3 characterised by mutual learning (Benzein et al. 2008).  
4 However, to our knowledge, the Health Promoting Conversations intervention has not been  
5 used in the context of ICU patients and their families. Furthermore, despite the mounting  
6 interest of Sweden and the Nordic countries in working with families from the perspective of  
7 family systems nursing (Flanagan, 2001), clinical interventions used in the family paradigm  
8 are often supported theoretically rather than empirically (Harmon Hanson et al., 2005;  
9 Östlund, 2010; Wright & Leahey, 2013). More experimental designs are needed to strengthen  
10 the evidence base of family nursing interventions, especially studies that produce empirical  
11 evidence (Östlund & Persson 2014). The present study aimed to fill some of these knowledge  
12 gaps by providing evidence of the effectiveness and clinical relevance of the Health  
13 Promoting Conversations intervention.

14

## 15 **Objective**

16 The objective was to investigate outcomes of a pilot randomised control trial (RCT), nurse-  
17 led Health Promoting Conversations intervention. This intervention was conducted with  
18 families and focussed on family functioning and wellbeing in families with a member who  
19 was formerly critically ill.

20

## 21 **Methods**

### 22 **Study design**

23 The study design was a pilot RCT with the intervention group undergoing the Health  
24 Promoting Conversations and the control group receiving usual care.

25

1 **Setting**

2 This pilot RCT study with identical interventions was performed in two intensive care units  
3 in South Eastern Sweden, one at a university hospital and one at a county hospital in the  
4 south east of Sweden. The intensive care units have capacities of 700 and 550 admissions per  
5 year, respectively.

6 **Sample/Participants**

7 The study included 17 families recruited consecutively, seven in the intervention group and  
8 ten in the control group. The inclusion criteria were as follows: patient age >18 years; patient  
9 treated in the ICU for at least 72 hours and alive; at least one family member (age >15 years)  
10 interested in participating. Nurses at the intensive care unit asked the patient if he or she and  
11 some of the family members were interested in participating in the study. The families who  
12 showed an interest were then contacted by the nurses (AE, IW) to obtain oral and written  
13 content.

14 Three weeks after each patient was discharged from the ICU, the nurse responsible for the  
15 Health Promoting Conversation intervention sent written information by mail about the study  
16 and then made a phone call to the patient to ask if he or she was interested in participating in  
17 the study. If a family member agreed to participate, the patient identified other family  
18 members, and they were also asked to participate. Both the patients and the family members  
19 had to understand Swedish and be able to sign an informed consent form. Before  
20 randomisation, the participants filled out baseline questionnaires. Families that chosed to  
21 participate were randomised to either the control or intervention group. The randomisation  
22 was performed by the statistician using the “Ralloc” procedure in Stata with blocks of 4. 1)  
23 the intervention group received traditional care with follow-up visits and a health-promoting  
24 conversation with their families; and 2) the control group received traditional care with  
25 follow-up visits. The interventions took place at the hospital in connection with a follow-up

1 visit. Follow-up visit were always conducted in a private room with only the patient, family  
2 and nurses present.

3

#### 4 **The Health Promoting Conversations intervention**

5 The patient and family members first discussed the aim of the intervention. The aim of the  
6 Health Promoting Conversations intervention is to create a context for change that was  
7 related to each family's identified problems and resources. The discussion also provided  
8 framework for the conversation series and discussed the expectations of the family and the  
9 nurses regarding the conversations and each other's roles. All family members were invited  
10 to tell their own stories and to listen to each other's stories about how they were experiencing  
11 the current situation. The conversation sessions focused on topics that each family considered  
12 important, and the dialogue and questions aimed to identify and make use of the resources  
13 available within and outside the family (Wright & Leahey, 2009).

14 In the intervention group, there were three health-promoting conversations with each family  
15 after the discharge. The health-promoting conversations were held within an approximately  
16 4- to 8-week period with an interval of 2 weeks between conversations. The first conversation  
17 lasted approximately 2 hours, and the two follow-up conversations lasted approximately 30–  
18 40 minutes. One or two research nurses who were not involved in the care of the patients had  
19 the conversations with the families. The nurses took responsibility for the conversations by,  
20 for example, asking reflecting questions.

21 At the end of each conversation, the nurses gave the family the chance to listen to a short  
22 reflection by the nurses summarising what they and the families had talked about. A closing  
23 letter was sent 2 to 3 weeks after the final conversation that summarised all of the  
24 conversations and provided further opportunities for reflection. To standardise the  
25 intervention, all participating research nurses completed formal theoretical education and

1 practical training related to the Health Promoting Conversations intervention at the School of  
2 Health and Caring Sciences, Linnaeus University, Kalmar, Sweden. All conversations were  
3 recorded, and adherence to the intervention was constantly evaluated.

#### 4 **The control group**

5 The patients and the partners in the control group received standard care, and nothing  
6 changed regarding treatment and follow-up during the time of the study. Standard care is  
7 addressed to the patient and concentrates on the patient's treatment and needs, including  
8 patient follow-up according to national guidelines. Although family members could follow  
9 the patients to hospital appointments, they were not systematically invited to participate  
10 during the visits.

11

#### 12 **Data collection**

13 Demographic self-reported data were collected during 2013- 2015 from the families.

14 Additional baseline data were collected to assess family functioning and wellbeing in the  
15 intervention group and the control group 1–2 months after the critical illness and before the  
16 start of the intervention. Follow-up assessments were conducted 3 and 12 months after the  
17 critical illness for both groups. Additionally, background data, including health history, were  
18 collected using a self-administered questionnaire that asked about age; sex; education level;  
19 habits like smoking, alcohol consumption, and physical activity; psychosocial support; co-  
20 morbidity; and risk of mortality (Charlson et al., 1987).

21 Based on a power calculation for this study using an unpaired t-test for a larger study, at least  
22 100 patients and family members were needed (50 in the intervention group and 50 in the  
23 control group) for the study. The calculation was based on a medium effect size ( $ES = 0.6$ ,  $\alpha$   
24  $= 0.05$ ;  $1-\beta = 0.8$ ). This pilot study was conducted to determine whether a larger study is  
25 merited, and this study included 17 families.

## 1 **Instruments**

2 The primary outcome variables in this study were family functioning and the secondary  
3 outcome variables were family wellbeing. The following instruments were used in this study:

- 4 1) General Functioning (GF) sub-scale from the McMaster Family Assessment Device  
5 (FAD); 2) Family Sense of Coherence (F-SOC/F-KASAM); 3) Herth Hope Index (HHI); and  
6 4) Medical Outcome Short-Form health survey (SF-36).

7

### 8 ***Family functioning***

9 Family functioning was assessed with the **GF sub-scale from the FAD** (Epstein et al.,  
10 Baldwin, & Bishop, 1983). The FAD is a 60-item self-reported questionnaire developed to  
11 assess family functioning within 7 dimensions (Alderfer et al., 2008), FAD was considered to  
12 have a very large evidence base and is one of the most well established family scales. This  
13 study only used the general functioning sub-scale (GF) since this sub-scale summarises  
14 family functioning well and has been recommended instead of the 60-item FAD (Ridenour et  
15 al., 1999). The GF is a 12-item scale designed to measure self-reported perceived overall  
16 family functioning (Wright and Leahey, 2009, 2013). Each item is rated on a four-point  
17 Likert scale: 'strongly agree' = 1, 'agree' = 2, 'disagree' = 3 and 'strongly disagree' = 4. The  
18 scale scores ranges from 12 to 48, with lower scores indicating better family functioning. The  
19 GF was translated into Swedish and has been pilot tested in Swedish samples, and the scale  
20 has shown satisfactory reliability and acceptable validity of 0.90 (Bylund et al., 2015).  
21 The reliability coefficient **Cronbach's alpha** was 0.86 (95% **CI** 0.72-0.94)  $p < 0.001$ , in this  
22 study.

23

### 24 ***Family wellbeing***

25 Family wellbeing was assessed with two instruments, F-SOC/F-KASAM and HHI.

1 **F-SOC/F-KASAM/stress** measures the perceived consequences of family life and successful  
2 management of family stress associated with family coherence. It has 3 dimensions,  
3 comprehensibility, manageability, and meaningfulness (Antonovsky and Sourani, 1988,  
4 Eriksson, Lindström 2005), which have all been theoretically and empirically linked to  
5 wellbeing. The questionnaire consists of 12 statements with Likert-type responses that are  
6 rated on a 7-point scale. The scale scores range from 12 to 84, with higher scores indicating a  
7 greater sense of coherence. The F-SOC has sound psychometric properties (Sagy and Dotan,  
8 2001). The scale was recently translated into Swedish and was pilot-tested (Möllerberg, in  
9 process.) The reliability coefficient **Cronbach's alpha** was 0.91 (95% **CI** 0.81-0.96)  $p < 0.001$ ,  
10 in this study.

11

12 The Herth Hope Index (**HHI**) was developed for use in advanced cancer patients (Herth,  
13 1992) and is based on a model developed by Dufault and Martocchio (1985). The instrument  
14 was translated into Swedish (HHI-S) and has been validated in a Swedish palliative  
15 population that included patients and their family members (Benzein and Berg, 2003). The  
16 instrument consists of 12 items scored on a Likert-type scale that ranges from 1 to 4, where 1  
17 represents 'strongly disagree' and 4 'strongly agree'. The total minimum score is 12, and the  
18 maximum score is 48. A higher score indicates a higher level of hope (Benzein and Berg,  
19 2003; Herth, 1992). The reliability coefficient **Cronbach's alpha** was 0.61 (95% **CI** 0.21-0.82)  
20  $p = 0.004$ , in this study.

21

## 22 ***Health-related quality of life***

23 The **SF-36** instrument was chosen for the evaluation of health-related quality of life  
24 (HRQoL). This instrument has been translated into Swedish and was validated in a  
25 representative sample of the population (Sullivan, 1995). The SF-36 is a generic 36-item

1 scale that evaluates HRQoL in 8 dimensions. The dimensions are weighed together in two  
2 consecutive indexes, a physical component score (PCS) and a mental component score  
3 (MCS). The physical index is made up of 4 dimensions: physical functioning, physical role  
4 functioning, bodily pain, and general health, The mental index also consists of 4 dimensions:  
5 vitality, social functioning, emotional role functioning, and mental health. The scores on all  
6 sub-scales are transformed to a scale from 0 to 100, where a higher score indicates better  
7 perceived health. The SF-36 is a well-established and frequently used instrument and has  
8 good reliability and validity (Ware, 1992). Most reliability estimates have exceeded the 0.80  
9 level (Ware, 1993). The reliability coefficient **Cronbach's alpha** was 0.93 (95% **CI** 0.87-0.97)  
10  $p<0.001$ , in this study.

11

## 12 **Data analysis**

13 Both descriptive and analytical statistical methods were used to analyse the data. Univariate  
14 methods were used to describe the sample. For comparisons of background variables between  
15 the intervention and control groups, the independent t-test, one-way ANOVA, repeated  
16 measures ANOVA, and  $\chi^2$ -tests were used. The Charlson Comorbidity Index Mixed model  
17 regression analysis was used to evaluate the hypothesised effects of the intervention. The  
18 level for statistical significance was set at  $p<0.05$ . Stata MP version 14.1 (StataCorp LLC,  
19 College Station, USA). A statistician was involved in the data analysis (MF).

20

## 21 **Ethical considerations**

22 This study conformed to the principles outlined in the Declaration of Helsinki (WMA 2013).  
23 Permission to perform the study was obtained from the Regional Ethics Review Board in  
24 Linköping, Sweden (Dnr 2013/228-31). The patients and their families were approached in a  
25 sensitive manner and were given verbal and written information about the study. They

1 provided written informed consent prior to their participation. Participants were informed  
2 during each conversation that they could withdraw from the study at any time without any  
3 effects on any future treatment and care. In addition, the participants were told that they could  
4 meet with a social worker if they wished, but the situation did not arise during the  
5 intervention. All recorded personal data and identifiable information were considered to be  
6 confidential and were stored securely.

7

## 8 **Results**

9 A total of 17 families with 45 family members were included in the pilot study at baseline  
10 and completed the demographic assessment (Figure 1). Three families with 15 family  
11 members did not complete the assessment at the 3-month time point, and an additional four  
12 families with eight members did not complete the assessment at the 12-month follow up. One  
13 patient was not alive after 12 months (report raw data 65% in the intervention group and 40%  
14 in the control group). We didn't ask the families the reason for this due to ethical reasons, but  
15 it was likely because of sickness and fatigue. Table 1 shows the clinical and demographic  
16 characteristics of the patients and families. Nearly 50% of the patients were female, and the  
17 majority of the family members were partners. "Not working" was dominant in individuals in  
18 both the control and intervention groups. Length of ICU stay for the control group was 8 days  
19 and for the intervention group 7 days.

20

### 21 **Family functioning – primary outcome**

22 Intervention families experienced a statistically significant improvement in family  
23 functioning (GF) from baseline to 12 months ( $p=0.03$ ; Table 2). The intervention families  
24 showed a statistically significantly increased family functioning (GF) from baseline to 3

1 months compared with the control group ( $p=0.005$ ; Appendix 1). The difference disappeared  
2 at 12 months.

### 3 **Family wellbeing – secondary outcome**

4 Family wellbeing, as measured by KASAM/stress, showed decreased stress in the  
5 intervention group after 3 months but not after 12 months compared with the control group.  
6 Hope (HHI) did not show greater improvement after 3 or 12 months in the intervention group  
7 compared with the control group. There were no significant differences between the groups  
8 (Figure 2).

9

### 10 **Health-related quality of life**

11 There was statistically significant increase in how the intervention families perceived two of  
12 the eight dimensions of the SF-36, namely social functioning (SF) ( $p=0.02$ ) and mental  
13 health (MH) ( $p=0.01$ ) from baseline to 12 months (Table 2). Although not statistically  
14 significant, an increase of 5 points or more was seen from baseline to 12 months in all eight  
15 dimensions for the intervention group and in four dimensions for the control group (GH, VT,  
16 SF, and RE), indicating clinically important improvement. We defined a clinical  
17 improvement in accordance with the developer of the instrument, i.e. an increase of 5 points  
18 or more (Ware, 2001; Dowdy, 2005). For the mental component score (MCS), the  
19 intervention group significantly increased over time compared with the control group  
20 ( $p=0.04$ ), increasing  $>5$  points between baseline and 3 months. No changes were seen in the  
21 intervention group over time.

22

### 23 **Patients vs. family members**

24 When the results for patients in the intervention and control groups were analysed, the results  
25 were similar to those found for the groups as a whole (i.e. for patients plus family members in

1 each group). The one exception was the HHI. For this instrument, hope was improved among  
2 the patients between baseline and 3 and 12 months when their data were analysed separately  
3 (data not shown; see Appendix 2). There were no significant differences.

4

## 5 **Discussion**

6 The present study evaluated the Health Promoting Conversations intervention (Benzein,  
7 Hagberg, & Saveman, 2008; Wright & Leahey, 2009), which was previously found to  
8 improve the health and wellbeing of patients in palliative care who were dealing with chronic  
9 illness (Benzein & Saveman, 2008; Benzein et al., 2015; Dorell et al., 2017). The new and  
10 important findings from this study are that the Health Promoting Conversations intervention  
11 improved family function over time, strengthened family wellbeing regarding stress in the  
12 short-term, and increased perceived HRQoL in terms of social functioning and mental health  
13 over time in family members of formerly critically ill patients. However, the Health  
14 Promoting Conversations intervention did not significantly affect short- or long-term family  
15 wellbeing regarding hope.

16 This is to our knowledge the first study to evaluate the effect of health promoting  
17 conversations of critical illness. Health-promoting conversations can benefit the entire family,  
18 not only the patient. This will prevent family ill-health and promote family functioning and  
19 well-being.

20 The level of stress decreased for the intervention group compared with the control group after  
21 the Health Promoting Conversations intervention. Changes in family roles or responsibilities  
22 and feelings of stress can be caused by, for example, being close to the patient and being out  
23 of work. This can create a constant state of uncertainty about future life related to critical  
24 illness may also cause stress (Frivold et al., 2016; Eggenberger and Nelms, 2007).

1 The intervention group had better family functioning from baseline to 12 months and a trend  
2 was seen that the stress level worsened over time for the control group. Healthy family  
3 functioning can support families and help them adhere to the situation. Moreover, healthy  
4 family relationships help support patients' physical and emotional health and that of the  
5 family as a unit (Bylund et al., 2015, Svenningsen et al. 2017).

6 The families that got the Health Promoting Conversations intervention perceived that their  
7 HRQoL improved significant over time in terms of social functioning and mental health, and  
8 5 scores in each eight dimensions indicated clinical improvement (Ware, 2001; Dowdy,  
9 2005). It was a difference between baseline and 3 months, i.e. after the first Health Promoting  
10 Conversation, and a follow-up visit at 12 months showed that this increase was maintained.  
11 Regarding the control group, we assume that follow-up visits could have positive effects on  
12 the families' mental health as well as promote even physical health. The summary component  
13 PCS and MCS increased over time for both the intervention and control groups, although  
14 these increases were only statistically significant for the MCS. Tilburgs et al (2015) shows  
15 that it is possible to positively influence the QOL after an ICU admission by providing social  
16 support from family and friends (Tilburgs, 2015).

17 The control group who got traditional follow-up visit at 3 months showed a trend to increase  
18 the level of hope. Family members having hope and hopefulness get positive energy and  
19 strength supporting the patient's wellbeing (Wåhlin, 2006). Hopelessness is an independent  
20 risk factor for mortality for previously critically ill patients (Orwelius, 2017); accordingly,  
21 support from family members is very important for the patient and has a significant impact on  
22 the patient's HRQoL (Tilburgs, 2015). In addition, in population-based studies and in other  
23 patient groups, hopelessness after critical illness is an independent predictor of risk of  
24 somatic disease and death (Garvin, 2009; Everson, 2000).

1 Another intervention study offered group communications for the partners of former ICU  
2 patients. Group communications contributed to a feeling of togetherness and confirmation.  
3 Sharing experiences with others in a similar situation is one way for partners to be able to  
4 move on in life  
5 (Ahlberg et al., 2015). Interventions based on focus groups or technology has been  
6 developed aiming at providing family support regarding information needs as well as coping  
7 strategies (Kirshbaum-Moriah et al. 2016, Chiang et al. 2017).  
8 To our knowledge, this is the first study to examine whether a Health Promoting  
9 Conversation intervention will be valuable for patients who have been critically ill and for  
10 their families in terms of improving family functioning and wellbeing. However, larger  
11 studies are needed to support results from this pilot study.

12

13 **Limitations**

14 The results in this study are preliminary, the study was rather small and a limitation is also  
15 that we do not have equal groups. However, this was a pilot study, and the positive results  
16 suggest that a larger study is warranted. Notably, however, the HHI scale showed a reliability  
17 coefficient of 0.61, which may indicate that the conclusions should be carefully considered  
18 (Benzein, Berg et al. (2003). In addition, 65% of the intervention families members and only  
19 40% of the controls completed the study at 12 months and may be related to fatigue and  
20 sickness of the patient and family members.

21

22 **Conclusion**

23 Health promoting conversations may improve family wellbeing by improving family  
24 function, reducing stress, and promoting better mental health. This study will add to clinical  
25 practice to support families affected by illness, whose support needs have often been

1 unrecognized and unsupported. Health promoting conversations will contribute to an  
2 evidence-based change of practice in the care of people with critical illness and their family  
3 members.

#### 4 **Implications for Clinical practice**

- 5 • Within the frame of “Health promoting conversations”, nurses have opportunities to  
6 mitigate suffering and to find relationship, space and language that work in synergy  
7 with families to support them in identifying own strengths and resources, learning and  
8 finding new strategies for managing their daily life.
- 9 • Excellent family nursing allows possibilities for the illness experience to become  
10 approachable and manageable in ways that respect the contextualized experience of  
11 those who are ill and their families.
- 12 • This will prevent family ill-health and promote family functioning and well-being.
- 13 • This study will therefore add to clinical practice to support families affected by  
14 illness, whose support needs have often been unrecognized and unsupported.

15

16

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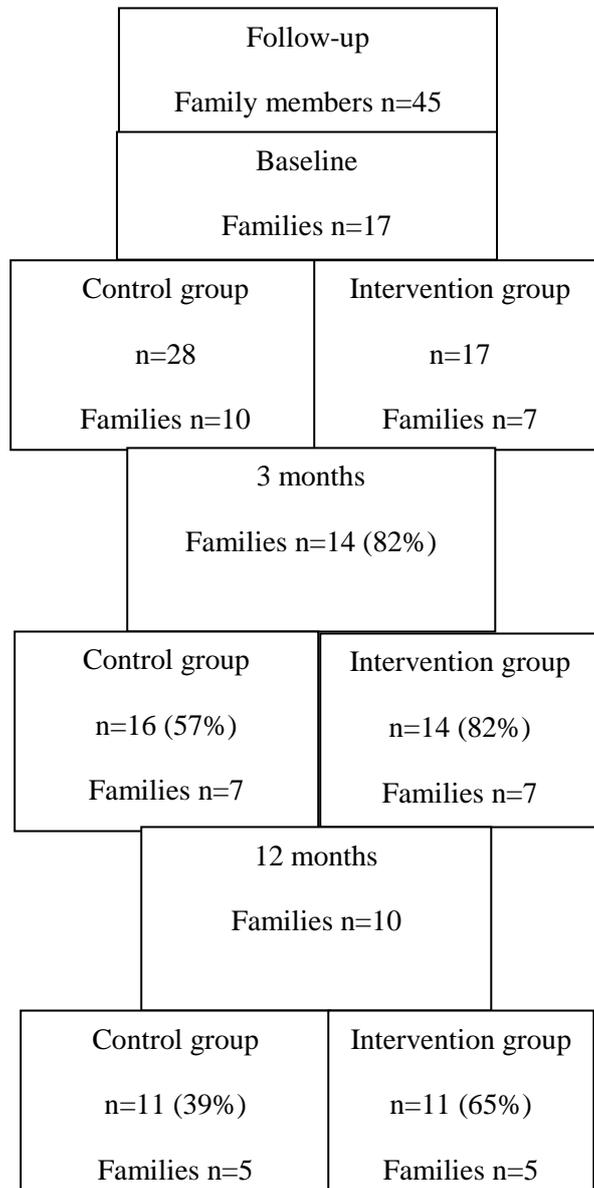
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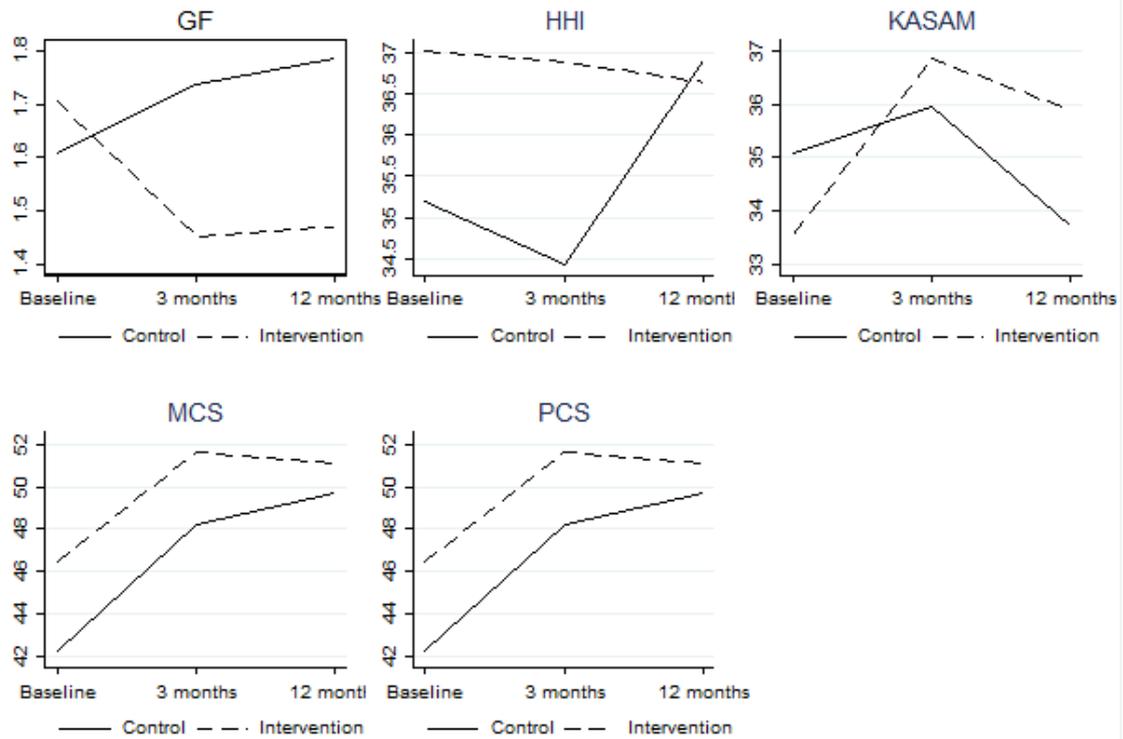
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**Figure 1.** A flowchart showing the family member participants throughout the clinical study.



**Figure 2.** Mean changes in General Functioning/Family Functioning (GF), Sense of Coherence/Stress (SOC/KASAM), Physical Health Score (PCS), Mental Health Score (MCS), and Herth Hope Scale (HHI) scores over time in the control and intervention groups. The number of individuals at each time point for each group is shown in Figure 1.



**Table 1** Sociodemographic and clinical characteristics of the 10 families (28 individuals) in the control group and the 7 families (17 individuals) in the intervention group for the Health Promoting Conversations intervention. There were a total of 45 participants.

	Control (total N=28)	Intervention (total N=17)	p value
	N (%)	N (%)	
Age, years; mean±SD	61±17	60±19	ns
Female	14 (50)	8 (53.3)	
BMI	27 (4.8)	26 (4.45)	
<b>Type of co-morbidity (%) risk</b>			ns
12-month mortality/10-year survival	7.93/61.47	6.45/60.27	
Myocardial infarction	2	0	< 0.001
Hypertension	6	5	< 0.001
Diabetes	5	2	ns
Stroke	2	2	ns
Lung disease	1	1	ns
<b>Education, N (%)</b>			ns
Elementary school or less	10 (35.8)	3 (17.6)	
High school	9 (32.1)	6 (35.4)	
University	8 (28.6)	5 (29.4)	
Missing data	1 (0.5)	3 (17.6)	
<b>Employment (%)</b>			ns
Full time	12 (42.9)	3 (17.6)	
Pension/disability pension/sick leave	15 (53.6)	11 (64.8)	
Missing data	1 (0.5)	3 (17.6)	
<b>Lifestyle (%)</b>			ns
Smoker/ex-smoker	4 (14.3)/24 (85.7)	1 (5.9)/13 (76.5)	
Missing data		3 (17.6)	
<b>Exercise</b>			< 0.001

0 min–3 hours/week	14 (56)	10 (58.8)
> 3 hours/week	12 (42.9)	5 (29.4)
Missing data	2 (1.1)	2 (11.8)

**Table 2.** Comparison between the control and intervention groups from baseline to 12 months.

		Control		p-value <sup>a</sup>	Intervention		p-value <sup>a</sup>	p-value <sup>b</sup>
		Mean(SD)	No.		Mean(SD)	No.		
GF	Baseline	1.6(0.4)	27		1.7(0.6)	17		0.09
	3 months	1.7(0.5)	16		1.4(0.5)	14		
	12 months	1.8(0.5)	11	0.33	1.5(0.6)	11	<b>0.03</b>	
KASAM	Baseline	35.1(9.3)	27		33.6(8.7)	17		<b>0.01</b>
	3 months	35.9(6.4)	16		36.8(10.2)	14		
	12 months	33.7(7.5)	11	0.5	35.9(9.1)	11	0.21	
HHI	Baseline	35.2(4.2)	27		37.0(3.4)	17		0.23
	3 months	34.4(5.4)	16		36.8(4.1)	14		
	12 months	36.9(2.9)	11	0.42	36.6(4.2)	11	0.54	
PF	Baseline	77.3(25.7)	26		67.9(32.7)	17		0.75
	3 months	79.3(29.1)	16		73.2(25.2)	14		
	12 months	77.3(30.1)	11	0.06	77.3(21.8)	11	0.34	
RP	Baseline	66.3(46.3)	26		45.6(44.4)	17		0.24
	3 months	73.4(41.3)	16		55.3(46.2)	14		
	12 months	70.4(40.0)	11	0.49	63.6(43.8)	11	0.67	
BP	Baseline	78.4(24.2)	26		58.0(27.2)	17		0.02
	3 months	81.2(17.4)	16		64.5(29.6)	14		
	12 months	78.7(22.4)	11	0.65	70.7(22.1)	11	0.3	
GH	Baseline	61.5(22.8)	26		61.9(20.9)	17		0.47
	3 months	69.1(22.7)	16		66.9(21.6)	14		
	12 months	70.1(19.8)	11	0.24	68.0(23.0)	11	0.51	
VT	Baseline	52.7(24.7)	26		57.0(24.4)	17		0.46
	3 months	64.7(23.6)	16		65.7(22.2)	14		
	12 months	64.1(18.3)	11	0.12	63.6(22.4)	11	0.22	
SF	Baseline	73.1(28.6)	26		61.8(30.8)	17		<b>0.01</b>
	3 months	85.2(20.5)	16		81.2(27.2)	14		
	12 months	84.1(25.1)	11	0.22	82.9(16.1)	11	<b>0.02</b>	
RE	Baseline	61.5(47.8)	26		64.7(39.9)	17		0.11
	3 months	75.0(41.3)	16		76.2(33.1)	14		
	12 months	87.9(30.8)	11	0.4	75.8(36.8)	11	0.65	
MH	Baseline	72.0(19.4)	26		75.3(15.2)	17		0.09
	3 months	79.0(17.4)	16		85.1(11.1)	14		
	12 months	76.4(15.6)	11	0.54	87.3(12.6)	11	<b>0.01</b>	
PCS	Baseline	47.2(12.0)	26		39.8(13.0)	16		0.54
	3 months	48.0(10.8)	16		41.6(14.7)	14		

	12 months	46.5(10.6)	11	0.44	44.0(8.1)	11	0.78	
MCS	Baseline	42.2(12.7)	26		46.5(10.8)	16		<b>0.04</b>
	3 months	48.2(10.5)	16		51.6(9.1)	14		
	12 months	49.7(6.7)	11	0.3	51.1(11.0)	11	0.26	

<sup>a</sup> p-value for comparison within group over time, from ANOVA for repeated measures.

<sup>b</sup> p-value for comparison between groups, mean over time, from ANOVA for repeated measures.

GF=Family function, KASAM=Stress measurement, HHI=Hope measurement, PF=physical functioning, RP=role functioning, BP=bodily pain, GH=general health, VT=vitality, SF=Social functioning, RE=role emotional, MH=mental health, PCS=physical component score, MCS=mental component score

**Appendix 1.** Mixed regression analysis of scores in the control and intervention groups from baseline up to 12 months after the intervention showing clusters of families.

	Mean change vs. reference	p-value	95% confidence interval
GF 3m vs. baseline			
Control	0.19	reference	0.01–0.36
Intervention	-0.36	<b>0.005</b>	-0.61– -0.11
GF 12m vs. baseline			
Control	0.08	reference	-0.31–0.46
Intervention	-0.22	0.67	-0.27–0.42
HHI 3m vs. baseline			
Control	-4.78	reference	-7.56– -1.99
Intervention	4.06	0.06	-0.14–8.27
HHI 12m vs. baseline			
Control	-0.09	reference	-1.67–1.48
Intervention	0.54	0.64	-1.69–2.77
KASAM 3m vs. baseline			
Control	-1.81	reference	-6.59–2.97
Intervention	4.64	0.46	-2.39–11.7
KASAM 12m vs. baseline			
Control	-0.83	reference	-5.16–3.49
Intervention	2.38	0.45	-3.74–8.50

PCS 3m vs. baseline			
Control	1.93	reference	-3.21–7.07
Intervention	-2.10	0.59	-9.75–5.55
PCS 12m vs. baseline			
Control	0.27	reference	-5.23–5.78
Intervention	1.98	0.63	-5.99–9.95
MCS 3m vs. baseline			
Control	2.96	reference	-1.34–7.28
Intervention	1.29	0.69	-5.15–7.73
MCS 12m vs. baseline			
Control	3.50	reference	-4.07–11.1
Intervention	1.68	0.76	-9.30–12.7
PF 3m vs. baseline			
Control	7.18	reference	-2.52–16.9
Intervention	-4.61	0.53	-18.8–9.59
PF 12m vs. baseline			
Control	5.91	reference	-3.96–15.8
Intervention	2.83	0.69	-11.1–16.8
RP 3m vs. baseline			
Control	7.81	reference	-12.4- 27.8
Intervention	-0.67	0.96	-29.9-28.5
RP 12m vs. baseline			
Control	0.64	reference	-36.6-37.9
Intervention	18.1	0.50	-34.6-70.7

BP 3m vs. baseline			
Control	-0.69	reference	-12.8- 11.4
Intervention	6.33	0.48	-11.3-24.0
BP 12m vs. baseline			
Control	-6.27	reference	-19.4–6.83
Intervention	20.5	<b>0.03</b>	2.01–39.1
GH 3m vs. baseline			
Control	3.83	reference	-3.89–11.6
Intervention	1.22	0.83	-10.1–12.5
GH 12m vs. baseline			
Control	5.80	reference	-5.83–17.4
Intervention	-1.55	0.85	-18.0–14.9
VT 3m vs. baseline			
Control	8.75	reference	-1.52–19.0
Intervention	0.89	0.91	-14.1–15.9
VT 12m vs. baseline			
Control	5.46	reference	-8.66–19.6
Intervention	5.27	0.60	-14.7–25.2
SF 3m vs. baseline			
Control	10.7	reference	-4.23–25.6
Intervention	5.82	0.60	-16.1–27.7
SF 12m vs. baseline			
Control	5.53	reference	-16.2–30.7
	19.4	0.29	-16.2–55.0

Intervention			
RE 3m vs. baseline			
Control	6.14	reference	-9.14–21.4
Intervention	0.62	0.96	-21.8–23.0
RE 12m vs. baseline			
Control	14.4	reference	-26.0–54.9
Intervention	1.31	0.96	-55.9–58.5
MH 3m vs. baseline			
Control	3.25	reference	-3.56–10.1
Intervention	6.18	0.22	-3.78–16.1
MH 12m vs. baseline			
Control	1.44	reference	-7.34–10.2
Intervention	11.6	0.07	-0.78–24.1

GF=Family function, HHI=Hope measurement, KASAM=Stress measurement, PCS=physical component score, MCS=mental component score, PF=physical functioning, RP=role functioning, BP=bodily pain, GH=general health, VT=vitality, SF=Social functioning, RE=role emotional, MH=mental health,

**Appendix 2.** General functioning/Family functioning (GF), Sense of Coherence/KASAM), Physical Health Score (PCS), Mental Health Score (MCS), and Herth Hope Scale (HHI) scores over time in patients and families in the control and intervention groups.

