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# UNIVERSITÀ DEGLI STUDI DI TORINO

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**Quality of life of primary caregivers of patients in a vegetative state receiving home enteral nutrition.**

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Short title: Home enteral nutrition and caregivers' wellbeing

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39 **Abstract**

40 Objective: To investigate the health-related quality of life and psychological well-being of caregivers of  
41 patients in a permanent vegetative state receiving home enteral nutrition, and to identify factors  
42 influencing their physical and psychological burden.

43 Patients and methods: Primary caregivers (N = 84) of patients in a vegetative state completed several  
44 questionnaires at home. The caregivers' sociodemographic characteristics (age, sex), caregiving  
45 contextual variables (amount of external help), objective stressors (environmental changes necessary  
46 to set up home enteral nutrition), subjectively perceived stress in managing the therapy, health-  
47 related quality of life, and psychological well-being were all assessed.

48 Results: The caregivers' health-related quality of life did not differ from that of the Italian population.  
49 The caregivers showed their satisfaction with the provision of home enteral nutrition and the constant  
50 support received to manage it. The most frequently reported advantages of home enteral nutrition  
51 were its friendly use and its unique role for the patient's health and well-being. However, depression,  
52 anxiety, and psychosomatic symptoms were frequently found in caregivers.

53 Conclusions: Once home care is well organized, it is important to provide psychological support to  
54 target the caregivers' psychological suffering and distress induced by assisting their severely disabled  
55 relatives.

56

57 **Key words:** Caregivers' wellbeing, patients in a vegetative state, home enteral nutrition

58

## 59 **1. Introduction**

60 Home enteral nutrition (HEN) allows nutrient intake in patients with inadequate or impossible  
61 oral feeding<sup>1</sup>. In this regard, HEN favours early hospital discharge for patients otherwise  
62 requiring long hospital stays<sup>2</sup>. This is especially true for patients affected by chronic  
63 neurovascular or neurodegenerative diseases, who are in a permanent vegetative state.

64 Previous studies, examining the burden of caregivers who assist patients in various clinical  
65 conditions<sup>4-9</sup>, have shown different levels of health deterioration, depression and  
66 psychological distress. However, only a few studies have examined the well-being of  
67 caregivers of patients who are terminally ill or in a vegetative state.<sup>10,11</sup>

68 According to the stress-coping model of Schulz et al.<sup>5</sup> and the well-being approach to  
69 health<sup>12,13</sup>, several objective and subjective stressors faced by caregivers may have an impact  
70 on their health related quality of life (HRQoL) and psychological wellbeing. In particular,  
71 Schulz et al.<sup>5</sup> proposed a model which includes the following contributors to and mediators of  
72 enduring outcomes of stressful life situations: (i) objective stressors, (ii) subjectively  
73 perceived stress, (iii) short-term responses to perceived stress at a physiological,  
74 psychological and behavioral level, (iv) enduring psychological and physical outcomes of  
75 perceived stress, and (v) conditioning variables such as the caregivers' individual  
76 characteristics, which may affect interaction between the other four categories of factors.

77 Figure 1 represents the hypothesized predictors of the caregivers' physical and psychological  
78 wellbeing considered in this study. The solid lines indicate the hypothesized causal  
79 relationships between factors, whereas the broken lines represent the possible mediating effect  
80 of conditioning variables on the relationship between factors. Each factor proposed by Schulz  
81 was taken into account except for the short-term responses to perceived stress (grey  
82 rectangle). Using this model as a guide and adopting a bio-psychosocial approach<sup>14-16</sup>, we

83 aimed at evaluating the possible influence of HEN management on the HRQoL and the  
84 psychological wellbeing of caregivers of non-independent patients in a vegetative state.  
85

## 86 **2. Methods**

### 87 *2.1. Research background: organisation of HEN in Italy*

88  
89 To facilitate the homecare of patients in a vegetative state, HEN is fully reimbursed by the  
90 healthcare system in Italy. The clinical and organizational aspects of HEN are supervised by a  
91 Nutritional Team (NT), which evaluates the patient's clinical condition, plans the nutritional  
92 therapy and provides training in HEN management for caregivers. Homecare is mainly  
93 monitored by primary care physicians who collaborate with the NT and the Local Social-  
94 Healthcare Districts (LSHD)<sup>3</sup>. The primary care physician visits the patient every 15-30 days,  
95 or more frequently if medical complications develop. Additionally, once a week a nurse of the  
96 LSHD visits the patient at home to administer medication, treat any pressure ulcers and check  
97 medical devices (e.g. feeding tubes, catheters). Moreover, a 7-h/day help-line for nutrition  
98 related issues and a 24-h/day technical help-line are available. HEN management is well-  
99 supported and organized in Italy. However, caregivers are confronted with a patient, who is  
100 usually a close relative, in a permanent vegetative state, and this may well influence their  
101 psychological and physical wellbeing.

102

### 103 *2.2. Participants and procedures*

104 Caregivers of patients in a vegetative state (Karnofski performance status  $\leq 40$ ) were  
105 identified by consulting an electronic database, which encompasses information on all  
106 patients receiving HEN in the province of Treviso, including the names of their caregivers.  
107 Caregivers were then contacted by phone to assess whether they were primary caregivers and  
108 whether they would consent to participate in the study, which involved filling in specific  
109 questionnaires, administered at home by a previously trained NT nurse.

110 Informed consent was obtained from all participants before administering the questionnaires  
111 and the study was carried out in accordance with the ethical standards of the Helsinki  
112 Declaration<sup>15</sup>.

113

### 114 *2.3. Measurements*

115 Conditioning variables. Gender, age, occupational status and parental relationship with the  
116 patient were considered the main conditioning variables. Additionally, the possible mediating  
117 effect of the following caregiving contextual variables was analyzed: the presence and type of  
118 external help, number of hours per week of external help, and number of months of caregiving  
119 since HEN began.

120 Objective conditions conducive to stress. The Environment Impact Evaluation scale (EIE)<sup>17</sup>  
121 was used to evaluate the objective environmental impact of HEN. The scale consists of a  
122 series of items with multiple-choice answers to assess the modifications required to manage  
123 HEN therapy at home (i.e., structural modifications, creation of special spaces, moving  
124 furniture or relocation of persons) and the costs borne to adapt the family home.



125 Perceived stress. One item of the EIE questionnaire asked caregivers to express their  
126 subjectively perceived degree of discomfort on a 4-point scale (0 = no discomfort at all, 3 =  
127 high discomfort) due to the environmental changes required to manage HEN. In addition,  
128 caregivers indicated their overall satisfaction with HEN on a 5-point scale (0 =not at all, 4 =  
129 very much), and filled in two forms on which they had to list the five main advantages and the  
130 five main disadvantages of HEN<sup>17</sup>. The reported advantages/disadvantages were divided into  
131 categories: 6 categories for the advantages (patient's survival, easy management of HEN,  
132 time/work load, nutritional aspects, patient's health/wellbeing, no advantage), and 5  
133 categories for the disadvantages (time/work load, technical problems with HEN, patient's  
134 health/wellbeing, emotional impact, no disadvantage).

135 Enduring outcomes. We used the Italian version of the SF-36<sup>18</sup> to assess the caregivers'  
136 HRQoL. This questionnaire entails 36 items that measure 8 aspects of general health: physical  
137 functioning, role limitations due to reduced physical functioning, bodily pain, general  
138 perception of health, vitality, social functioning, role limitations due to emotional problems,  
139 and mental health. Italian population norms for the 8 scales of the SF-36 are available<sup>18</sup>.

140 Psychological wellbeing. The caregivers' psychological wellbeing was assessed with a subset  
141 of scales of the SCL-90 developed by Derogatis, Lipman and Covi<sup>19</sup>. The SCL-90 entails 9  
142 subscales that measure various types of psychopathologies while single subscales are often  
143 used for specific diagnoses<sup>20</sup>. In this study, participants were asked to check the symptoms  
144 pertaining to the subscales of psychosomatic symptoms, depression, anxiety and interpersonal  
145 sensitivity by indicating how frequently they experienced each of 44 symptoms during the  
146 previous week on a 5-point scale (0 = not at all, 4 = extremely). Derogatis<sup>21</sup> has suggested a  
147 cut-off ( $t$  score  $\geq 63$ , 90<sup>th</sup> percentile) to identify clinically relevant cases, whereas, to our  
148 knowledge, there are no normative data for the Italian population.

149

150 *2.4. Statistical Analysis*

151 Data analyses were conducted with SPSS software, version 15.00 for Windows. Descriptive  
152 statistics were calculated for all independent and dependent variables, including range, mean  
153 and standard deviation for the continuous variables and percentages for the categorical  
154 variables. Associations between the caregivers' sociodemographic characteristics and the  
155 caregiving contextual variables were examined by Chi-square tests and ANOVA analysis.  
156 Furthermore, the caregivers' scores on the 8 SF-36 scales, adjusted for the effects of age and  
157 gender, were compared with the norm for the Italian population by using single sample  
158 Student's *t* tests. In addition, a General Linear Model (GLM) analysis was computed,  
159 measured by the SF-36, to examine the explanatory effects of all independent variables  
160 (conditioning variables, objective stressors, perceived stress) on the caregivers' HRQoL.  
161 Finally, by calculating logistic regressions, we investigated whether the independent variables  
162 can predict clinically relevant cases of somatization, depression, anxiety and interpersonal  
163 sensitivity, as measured by the SCL-90.

164

165

### 166 3. Results

#### 167 3.1. Descriptive results

168 Among the 153 caregivers contacted, 14 (9.2%) did not agree to participate in the study and  
169 55 (35.9%) were excluded from the study for the following reasons: 41 (26.8%) were not the  
170 patients' primary caregivers, 12 (7.8%) were the caregivers of patients who had been admitted  
171 to hospital, and 2 (1.3%) caregivers had lost their patients as a result of death.

172 The final sample included 84 primary caregivers (85.7% of the eligible participants) of  
173 patients in a vegetative state who agreed to participate and fill in the questionnaires. The  
174 patients assisted by the caregivers included 58 women and 26 men aged 23 - 97 years old  
175 ( $77.3 \pm 14.2$  years). The vegetative state of the patient was caused by a cerebrovascular  
176 accident or a degenerative disease such as Parkinson's or Alzheimer's.

177 Conditioning variables. Descriptive statistics of the sociodemographic characteristics of the  
178 caregivers and the caregiving contextual variables are shown in Table 1. Caregivers, mostly  
179 female in the 55-74 age group, were not professionally active, and were either the patient's  
180 spouse or daughter/son. With regard to the caregiving contextual variables, only 10 caregivers  
181 received no external help whereas the others received help, either from relatives or from  
182 professional caregivers. The amount of external help varied greatly from 0 - 168 hours per  
183 week while the duration of caregiving showed high variance ranging from 2 - 84 months.  
184 The Chi-square test revealed that the caregivers' sociodemographic characteristics and the  
185 presence and type of external help were significantly associated for gender [ $X^2(2, N = 84) =$   
186  $6.54, p < .05$ ] and occupational status [ $X^2(2, N = 84) = 8.26, p < .05$ ]. In particular, more  
187 female (18.5%) than male (0%) caregivers received no external help, and fewer female  
188 (38.9%) than male (53.3%) caregivers received help from a professional caregiver. As for  
189 occupational status, professionally active caregivers were more likely to obtain professional  
190 help (66.7%) than caregivers who do not work or are retired (33.3%), the latter receiving

191 more help from relatives or friends (52.6%) than the professionally active caregivers (25.9%).  
192 ANOVA analysis revealed the effects of the caregivers' sociodemographic characteristics on  
193 the amount of hours per week of external help and caregiving duration, by showing an effect  
194 of gender [ $F(1,82) = 5.00, p < .05$ ] and age group [ $F(4,79) = 3.16, p < .05$ ], but only on hours  
195 per week of external help. In particular, women ( $M = 55.24, SD = 59.71$ ) received fewer hours  
196 per week of external help than men ( $M = 84.70, SD = 54.30$ ) while caregivers aged over 74  
197 years old received many more hours per week of external help ( $M = 109.00, SD = 65.48$ ) than  
198 the caregivers of the other age groups.

199 Objective conditions conducive to stress: Environmental Impact of HEN. In order to take care  
200 of the patients at home, 61 caregivers reported that modifications were needed in the home  
201 environment (Table 1). In 25% of cases, remodelling was related to structural parts of the  
202 house (walls, floors and staircases) whereas in the remaining cases remodelling was limited to  
203 the renewal/adaptation of the bathroom and the electric/heating/ventilation systems.  
204 Furthermore, several functional changes in the use of rooms and furniture were reported  
205 (47.6%): in some cases the patient's room had to be relocated; in others, furniture had to be  
206 moved or removed or the rooms' assigned to family members had to be changed. The  
207 reported costs of modifications exceeded €500 in 24 cases.

208 Subjectively perceived stress. The modifications needed to set up HEN generally caused only  
209 little subjectively perceived discomfort (Table 1). In fact, caregivers reported no discomfort in  
210 50 cases (59.5%), low to moderate discomfort in 32 cases (38.1%) and high discomfort in 2  
211 cases (2.4%).

212 Similarly, caregivers were overall very satisfied with HEN (Table 1). Only one caregiver  
213 (1.2%) was little satisfied, and only 5 caregivers (6%) were moderately satisfied with HEN,  
214 whereas the remaining 78 (92.8%) were much (48.8%) or very much (44.0%) satisfied. This  
215 rather high level of satisfaction with HEN is also supported by the qualitative analysis of the

216 reported advantages and disadvantages of HEN (Table 1). Among the 84 caregivers, only 2  
217 (2.4%) reported that HEN has no advantage and 2 (2.4%) did not fill out this item. Taking  
218 into account the overall advantages (N = 149), 28.2% related to the easy management of HEN  
219 (e.g. “Handy”, “Comfortable”, “Excellent and punctual delivery service by very efficient  
220 staff”), 22.1% referred to the patient’s health/wellbeing (i.e., “the patient is calmer”, “the  
221 patient had no more complications”), 17.5% to a reduction in the time and work load (i.e.,  
222 “No more need to prepare, or whip special food”), 14.8% to nutritional aspects (i.e.,  
223 “Adequate calorie intake”), and 14.8% to the patient’s survival (i.e., “ the patient is still  
224 alive”). Finally, 4 answers (2.7%) could not be categorized.

225 With regard to the disadvantages, 29 (34.5%) caregivers did not report any for HEN, whereas  
226 3 (3.6%) caregivers did not complete the item. If disadvantages were reported (N = 88), they  
227 mostly (34.1%) concerned technical problems encountered during the use of HEN (i.e.  
228 “Problems with the feeding tube”), followed by problems related to the patient’s  
229 health/wellbeing (30.7%; i.e. “Increase in weight”) and the time and work load involved in the  
230 management of HEN (23.9%; i.e. “the patient needs more time”). Nine disadvantages (10.2%)  
231 referred to the negative emotional impact of HEN (i.e., “Suffering when seeing the patient in  
232 this condition”) and, finally, 1 disadvantage (1.1%) could not be categorized.

233 Overall, the number of reported advantages was significantly higher than the number of  
234 reported disadvantages [ $t(83) = 5.23, p < .001$ ]. For further analyses, and for each caregiver, a  
235 summary score was calculated by subtracting the number of reported disadvantages from the  
236 number of advantages .

237 Enduring outcomes: Health-related quality of life and psychological wellbeing. Descriptive  
238 statistics of the 8 scales of SF-36, stratified according to gender and age groups are reported in  
239 Table 2. AMANOVA analysis, which was used to test whether there were differences in  
240 HRQoL related to age and gender within our sample, showed the main effect of age [ $F(32,$

241 280) = 1.56,  $p < .05$ ]. Univariate statistics indicated that age had a significant influence on the  
 242 scores of Physical Functioning [ $F(32, 280) = 10.75, p < .001$ ], Role-Physical [ $F(32, 280) =$   
 243 7.63,  $p < .001$ ], and General Health [ $F(32, 280) = 4.78, p < .01$ ]. In particular, the scores  
 244 decreased with increasing age especially among the over 74-year olds.

245 Comparing the age- and gender- adjusted mean scores of the caregivers to the Italian norms,  
 246 the only significant difference concerned General Health, for which caregivers scored higher  
 247 than the Italian population (Table 3).

248 The results of the four assessed subscales of SCL-90 are reported in Table 4 for the whole  
 249 group of caregivers, for males and females separately, and for age groups separately. Overall,  
 250 caregivers who exceeded the clinical cut-off ( $t$  score  $\geq 63$ ) showed an incidence of 17.9% for  
 251 depression, 15.5% for psychosomatic symptoms, 9.5% for anxiety, and 7.1% for interpersonal  
 252 sensitivity. Although at a descriptive level, female caregivers showed a higher incidence of  
 253 symptoms than male caregivers, especially for somatization and anxiety, the older age groups  
 254 seemed more affected by psychopathology (especially depression for those  $>74$  years) than  
 255 the younger ones while Chi-square tests indicated that there were no significant associations  
 256 between the incidence of symptoms and either gender, nor age groups.

257

### 258 *3.2. Effect of predictor variables on enduring outcomes*

259 General linear model (GLM) to test the effect of the predictor variables on the 8 SF-36 scales.

260 The multiple GLM on SF-36 scales yielded significant effects for the oldest age group ( $> 74$   
 261 years) and perceived discomfort due to the environmental changes necessary to set up HEN  
 262 (Table 5).<sup>1</sup> Univariate follow-up analysis showed that the oldest age group scored lower on  
 263 physical functioning [ $F(1, 66) = 11.37, p < .01$ ], role limitations due to reduced physical

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<sup>1</sup> Given the interaction of some caregivers' characteristics and caregiving contextual variables, a further GLM was run with the addition of the following interactions: gender x type of help, occupational status x type of help, gender x hours per week of help, and age over 74 x hours per week of help. No significant interaction effect was found, whereas the main effect of discomfort for environmental changes held [ $F(8, 54) = 3.14, p < .01$ ] and the effect of age over 74 remained marginally significant [ $F(8, 54) = 1.90, p = .07$ ].

264 functioning [ $F(1, 66) = 20.72.63, p < .001$ ], bodily pain [ $F(1, 66) = 4.08, p < .05$ ], general  
265 health [ $F(1, 66) = 8.85, p < .01$ ], and vitality [ $F(1, 66) = 7.01, p < .01$ ] than the younger age  
266 groups. Moreover, estimated parameters showed that the higher the caregivers' discomfort  
267 due to the environmental changes necessary to set up HEN, the lower their scores on physical  
268 functioning ( $B = - 7.29, p < .05$ ), bodily pain ( $B = - 14.75, p < .01$ ), general health ( $B = -$   
269  $12.28, p < .01$ ), vitality ( $B = - 8.07, p < .05$ ), social functioning ( $B = - 13.35, p < .01$ ), role  
270 limitations due to emotional problems ( $B = - 18.22, p < .05$ ), and, finally, mental health ( $B = -$   
271  $12.84, p < .001$ ).

#### 272 Logistic binary regressions to test the effect of the predictor variables on the 4 SCL-90 scales

273 Logistic binary regressions (enter method) showed no significant effects on somatization,  
274 interpersonal sensitivity, and anxiety scales, whereas, with regard to depression, a test of the  
275 full model (including all predictor variables) versus a model with the intercept only, was  
276 statistically significant [ $X^2(15, N = 84) = 27.59, p < .05$ ], and could improve the rates of  
277 correct classifications. The model was able to correctly classify 98.6% of those who were not  
278 depressed and 46.7% of those who were depressed, with an overall success rate of 89.3 %  
279 (versus 82.1% of the model with the intercept only). Predictors that had significant effects  
280 included structural modifications ( $B = - 3.87, p < .01$ ), and discomfort due to environmental  
281 modifications necessary to set up HEN in the home environment ( $B = 2.27, p < .01$ ). The odds  
282 ratio for structural modifications indicates that caregivers who made structural modifications  
283 were .021 times less likely to be depressed than caregivers who did not, whereas feeling one  
284 point more of discomfort enhances the probability of being depressed by 9.72 times.

285

286

#### 287 **4. Discussion**

288 The study examined the effect of managing HEN, for patients in a vegetative state, on  
289 caregivers' HQRoL and subjective well-being. Guided by the model of Schulz et al.<sup>5</sup>, we took  
290 into account the possible impact of conditioning variables, objective stressors and subjectively  
291 perceived stress on these enduring outcomes.

292 When HRQoL (measured with SF-36) is taken into consideration, the caregivers had similar  
293 results to the Italian norm group, although they reported better general health. Moreover,  
294 inferential statistics showed that being aged over 74 years old and feeling high discomfort due  
295 to the environmental changes required to set up HEN, were significant predictors of lower  
296 HRQoL. Contrary to the results of previous studies<sup>6-8, 22, 23</sup>, our caregivers did quite well.  
297 These previous studies suggest that although caregivers are constantly subjected to a high  
298 level of stress, there is a strong relationship between the patient's physical and cognitive  
299 disabilities and therefore the amount of their daily needs, and their caregivers' well-being.  
300 Indeed, studies on caregivers of highly demanding patients, i.e., patients affected by  
301 Alzheimer's disease<sup>22</sup>, cancer<sup>23</sup>, mechanical ventilation<sup>24</sup> or a stroke<sup>25</sup>, found that lack of  
302 social support, the poor functional status of patients and the patient's cognitive impairment  
303 were the factors more closely related to an increase in the caregivers' burden. Also Brazil et  
304 al.<sup>11,26</sup>, analysing caregivers' needs, found that assisting the patient in activities of daily living  
305 is the most important predicting factor of a high burden. Being in a vegetative state, our  
306 patients do not need to be taken around and helped in daily living activities, but mostly need  
307 to be assisted with feeding and mobilization to avoid pressure sores. To fulfill these every day  
308 needs of patients, the caregivers in this study receive well-structured help and an easy to  
309 manage tool, i.e., HEN. The daily assistance of the patients in this study is managed by the  
310 collaboration between the caregivers, the NT, and the family physician. In addition, the  
311 financial support provided in the case of HEN, very often allows caregivers to hire somebody



312 for extra help. Moreover, the caregivers reported that they were generally very satisfied with  
313 HEN. They indicated the ease of its management and its necessity for the patients' health as  
314 the main advantages, whereas they reported only a few disadvantages, even in those cases  
315 where HEN required major or minor changes to the home in order to be set up. In fact, these  
316 changes caused high levels of reported discomfort in only 2.4% of the caregivers. Thus it  
317 seems that the caregivers mostly focused on the advantages of HEN in assisting the patient at  
318 home and in preserving his/her health. To sum up, these results suggest that factors such as  
319 help from the primary care physician and a weekly visit by a nurse, external formal or  
320 informal help, the easy management of HEN, and the fact that the patients do not show signs  
321 of physical or cognitive pain<sup>10,27</sup> can lead to a reduction in the caregivers' burden and could  
322 explain their rather high HRQoL.

323 Despite this rather positive outcome on HRQoL, results of the SCL90 scales showed that the  
324 number of caregivers who exceeded the clinical cut-off was rather high, especially for  
325 depression. Again, only two predictor variables, the need of structural modifications in the  
326 home to set up HEN and perceived discomfort due to environmental modifications, had a  
327 significant impact.

328 As pointed out by Herbert et al.<sup>10</sup>, pain and suffering are often used as synonyms, however  
329 they do not indicate the same concept. Our caregivers showed better general health than the  
330 Italian norm group, and they reported that they were able to manage the HEN therapy at  
331 home. Nonetheless, their psychological suffering should not be ignored, as they are taking  
332 care of their severely ill beloved relatives<sup>28</sup>. Although more attention has been paid to the  
333 point of view of the caregivers of HEN patients<sup>17,29</sup> and there is increased awareness of the  
334 risks of their burden due to assisting a chronically ill person at home, less attention has been  
335 paid to understanding what kind of support is needed in order to reduce the caregivers' stress.

336

337 **5. Conclusions**

338 When the location of therapy is moved from the hospital to the patients' homes, the  
339 assessment of the impact of managing the therapy should take into account all the facilitators  
340 that can be activated. Since we did not find a negative impact on the caregivers' HRQoL, we  
341 think that this is mainly due to the fact that the service provided is effective in reducing their  
342 strain. In particular, frequent practical and structured help offered daily in managing the  
343 therapy seems to be the most important factor in reducing their burden<sup>30</sup>. Nevertheless, the  
344 caregivers complain of psychological suffering. This result suggests that once the stressors  
345 linked to everyday caregiving tasks are effectively reduced, attention should be paid to the  
346 support needed to face the psychological aspects, especially the anticipatory grief the  
347 caregivers may experience while taking care of their relative.<sup>31</sup>

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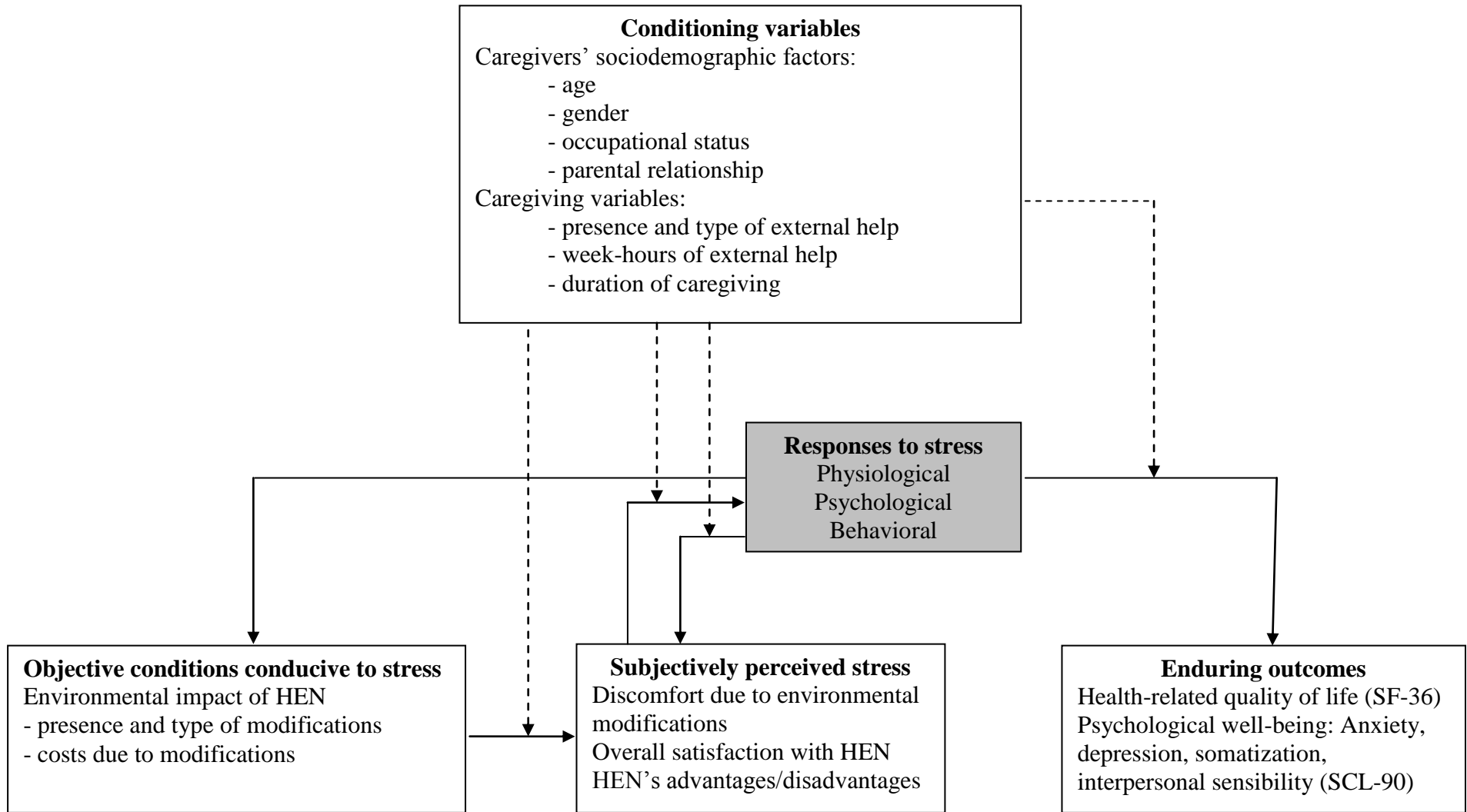
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437



439 Fig. 1. Caregiving coping model and variables considered in this study. HEN = Home enteral nutrition  
 440







443 Table 1  
444 *Descriptive statistics of independent variables*

	<i>n</i>	<i>%</i>	<i>M ± SD</i>	<i>Range</i>
<i>Caregivers' sociodemographic factors</i>				
Gender				
Male	30	35.7		
Female	54	64.3		
Age				
35-44	9	12.0	61.4 ± 11.5	40-87
45-54	15	17.9		
55-64	25	28.5		
65-74	24	28.5		
>74	11	13.1		
Occupational status				
Homemaker or retired	57	67.9		
Professionally active	27	32.1		
Parental relationship with patient				
Spouse	30	35.7		
Daughter or son	36	42.9		
Other relative or friend	18	21.4		
<i>Caregiving contextual variables</i>				
Presence and type of help				
Professional help	37	44.0		
Help from relatives	37	44.0		
No help	10	12.0		
Week-hours of help			65.8 ± 59.6	0-168
Months of caregiving duration			25.2 ± 19.4	2-84
<i>Environmental impact of HEN</i>				
Presence and type of modifications				
No modifications	23	27.4		
Structural modifications	21	25.0		
Other modifications	40	47.6		
Costs of modifications				
No costs	23	27.4		
< 500 €	37	44.0		
> 500 €	24	28.6		
<i>Perceived stress</i>				
Discomfort due to environmental impact of HEN			0.57 ± 0.80	
Overall satisfaction with HEN			3.36 ± 0.65	
Advantages			1.75 ± 0.99	
First	80	95.2		
Second	47	56.0		
Third	19	22.6		
Forth	3	3.6		
Disadvantages			0.70 ± 1.49	
First	52	61.9		
Second	23	27.4		
Third	8	9.2		
Forth	5	6.0		
HEN's advantages - disadvantages			1.05 ± 1.84	

446 Table 2

447 *Cargivers' mean scores on the 8 SF-36 scales divided by gender and age*

Age	Gender	n	SF-36 scales															
			PF		RP		BP		GH		VT		SF		RE		MH	
			M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD
35-44	M	3	96.7	2.9	100.0	0.0	91.3	15.0	64.7	13.3	63.3	37.9	79.2	26.0	66.7	57.7	54.7	28.4
	F	6	91.7	8.2	87.5	30.6	69.3	25.6	76.2	23.5	62.5	31.4	64.6	37.4	77.8	40.4	69.3	32.4
45-54	M	8	95.6	6.2	81.2	34.7	81.9	27.3	84.3	10.4	65.6	12.7	76.6	33.0	87.5	35.4	74.0	11.9
	F	7	91.7	10.1	91.4	14.9	78.3	28.3	66.7	25.6	60.0	20.2	87.5	14.4	85.7	26.2	70.3	19.7
55-64	M	8	93.1	8.0	93.4	11.6	81.9	26.7	73.9	14.9	66.9	20.5	68.8	22.2	87.5	24.8	69.5	26.5
	F	17	67.9	25.9	51.5	48.0	57.2	32.3	51.4	22.3	48.8	14.5	61.0	25.3	62.7	43.9	56.0	14.3
65-74	M	5	87.0	20.8	100.0	0.0	86.0	13.6	75.6	15.6	77.0	12.0	80.0	25.9	100.0	0.0	73.6	16.6
	F	19	68.4	25.6	53.9	41.9	52.2	27.8	52.7	21.8	39.5	16.1	55.3	26.8	57.9	41.3	54.2	19.1
> 74	M	6	32.5	16.4	12.5	13.7	51.2	40.1	30.0	23.0	42.5	17.2	52.1	32.0	55.6	50.2	47.3	29.0
	F	5	60.0	20.3	25.0	43.3	63.0	27.1	53.8	4.8	43.0	16.0	82.5	20.9	66.7	47.1	48.8	9.1
Total	M	30	81.0	27.4	75.8	38.0	77.4	29.3	67.2	24.7	63.0	20.9	70.4	28.3	81.1	36.8	65.5	23.6

F 54 73.1 24.3 59.1 47.7 60.1 28.5 56.8 22.6 48.0 19.5 64.8 27.6 66.0 40.7 58.1 19.5

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448

449 Table 3

450 *SF-36: Comparison between caregivers and the Italian norm data*

SF-36 scales	Caregivers		Italian population <sup>a</sup>		Mean differences	<i>p</i>
	(N = 84)		(N = 1471)			
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>		
PF	84.01	21.32	80.32	19.11	3.69	ns.
RP	77.89	36.67	73.63	34.34	4.26	ns.
BP	73.80	27.77	69.88	25.73	3.92	ns.
GH	66.22	21.93	61.17	19.84	5.05	< .05
VT	59.11	22.83	59.44	19.56	-.33	ns.
SF	71.90	27.07	75.60	22.58	-3.70	ns.
RE	76.83	37.75	73.12	36.82	3.71	ns.
MH	63.91	22.27	64.41	20.03	-.50	ns.

451 <sup>a</sup> Age of the general Italian population was adjusted to the caregivers sample.

452

453 Table 4

454 *Incidence (in %) of depression, somatization, anxiety and interpersonal sensitivity in*455 *caregivers*

SCL-90 scales	Total	Gender		Age groups				
		Males	Females	35-	45-54	55-64	65-74	> 74
	<i>N</i> =	<i>n</i> =	<i>n</i> = 54	44				
	84	30		<i>n</i> = 9	<i>n</i> =	<i>n</i> =	<i>n</i> =	<i>n</i> =
					15	25	24	11
Depression	17.9	13.3	20.4	11.1	13.3	20.0	12.5	36.4
Somatization	15.5	6.7	20.4	11.1	6.7	20.0	20.8	9.1
Anxiety	9.5	3.3	13.0	11.1	6.7	4.0	16.7	9.1
Interpersonal sensitivity	7.1	6.7	7.4	11.1	0.0	16.0	0.0	9.1

456

457

458 Table 5  
 459 *Multivariate effects of independent variables on the 8 SF-36 scales*  
 460

Variables	<i>F</i> (8,60)	<i>p</i>
<i>Caregivers' sociodemographic factors</i>		
Female gender	1.67	ns.
Age (< 45 as reference)		ns.
45-54	0.76	ns.
55-64	1.22	ns.
65-74	1.25	ns.
>74	2.80	.011
Occupational status (no as reference)	1.68	ns.
Relationship (other as reference)		
Spouse	1.20	ns.
Daughter or son	1.15	ns.
<i>Caregiving variables</i>		
Type of help (professional as reference)		
Help from relatives	0.40	ns.
No help	0.52	ns.
Week-hours of help	0.55	ns.
Caregiving duration	1.00	ns.
<i>Environmental impact of HEN</i>		
Type of modifications (no as reference)		
Structural modifications	1.83	.090
Other modifications	1.49	ns.
Costs of modifications	-- <sup>a</sup>	
<i>Perceived stress</i>		
Discomfort for environmental modifications	3.52	.002
Overall satisfaction with HEN	1.75	ns.
HEN's advantages - disadvantages	1.037	ns.

461 Notes:

462 <sup>a</sup> Since costs of modifications showed a high positive correlation with discomfort due to  
 463 environmental modifications ( $r = .73$ ), this variable has not been considered in the analysis to  
 464 avoid problems of collinearity.

465 Only p values below .10 are reported.

466

467

468