Published in final edited form as:

Am Heart J. 2010 April ; 159(4): 627–634.e7. doi:10.1016/j.ahj.2010.01.013.

Quality of Life Effects of Automatic External Defibrillators in the Home: Results from the Home Automatic External Defibrillator Trial (HAT)

Daniel B. Mark, M.D., M.P.H.¹, Kevin J. Anstrom, Ph.D.¹, Steven E. McNulty, M.S.², Greg C. Flaker, M.D.³, Andrew M. Tonkin, M.D., F.R.A.C.P.⁴, Warren M. Smith, B.S., M.B., F.R.A.C.P.⁵, William D. Toff, M.D.⁶, Paul Dorian, M.D.⁷, Nancy E. Clapp-Channing, R.N., M.P.H.¹, Jill Anderson, R.N., B.S.N.¹⁰, George Johnson, B.S.E.E.¹⁰, Eleanor B. Schron, R.N., Ph.D.⁸, Jeanne E. Poole, M.D.⁹, Kerry L. Lee, Ph.D.², and Gust H. Bardy, M.D.¹⁰

¹ Outcomes Research Group, Durham, NC ² Duke Clinical Research Institute, Durham, NC ³ University of Missouri, Columbia, Missouri ⁴ Monash University, Victoria, Australia ⁵ Auckland City Hospital, Auckland, New Zealand ⁶ University of Leicester, Leicester, England ⁷ University of Toronto, Toronto, Ontario ⁸ National Institutes of Health, Bethesda, Maryland ⁹ University of Washington, Seattle, Washington ¹⁰ Seattle Institute for Cardiac Research, Seattle, Washington

Abstract

Background—Public access automatic external defibrillators (AEDs) can save lives, but most deaths from out-of-hospital sudden cardiac arrest occur at home. The Home Automatic External Defibrillator Trial (HAT) found no survival advantage for adding a home AED to cardiopulmonary resuscitation (CPR) training for 7001 patients with a prior anterior wall myocardial infarction. Quality of life (QOL) outcomes for both the patient and spouse/companion were secondary endpoints.

Methods—A subset of 1007 study patients and their spouse/companions was randomly selected for ascertainment of QOL by structured interview at baseline and 12 and 24 months following enrollment. The primary QOL measures were the Medical Outcomes Study 36-Item Short-Form (SF-36) psychological well-being (reflecting anxiety and depression) and vitality (reflecting energy and fatigue) subscales.

Results—For patients and spouse/companions, the psychological well-being and vitality scales did not differ significantly between those randomly assigned an AED plus CPR training and controls who received CPR training only. None of the other QOL measures collected showed a clinically and statistically significant difference between treatment groups. Patients in the AED group were more likely to report being extremely or quite a bit reassured by their treatment assignment. Spouse/

Address for Correspondence: Daniel B. Mark, MD, MPH, Director, Outcomes Research, Duke Clinical Research Institute, P.O. Box 17969, Durham, NC 27715, daniel.mark@duke.edu, 919-668-8775 (Phone), 919-668-7060 (Fax).

Clinical Trials Registration Number: ClinicalTrials.gov number, NCT00047411
<http://clinicaltrials.gov/ct2/show/NCT00047411?term=HAT&rank=9>

DISCLOSURES

Dr. Mark reports receiving research support from Medtronic; Dr. Smith, having stock options in Cameron Health; Dr. Poole, receiving research support from Biotronik, participating in the speaker's bureaus for and receiving honoraria from Medtronic, St. Jude Medical, and Boston Scientific; Dr. Bardy, consulting for Philips Medical Systems.

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companions in the AED group reported being less often nervous about the possibility of using AED/CPR treatment than those in the CPR group.

Conclusions—Adding access to a home AED to CPR training did not affect quality of life either for patients with a prior anterior myocardial infarction or their spouse/companion but did provide more reassurance to the patients without increasing anxiety for spouse/companions.

Keywords

Cardiopulmonary resuscitation; sudden cardiac arrest; automated external defibrillator; quality of life; emergency medical services

INTRODUCTION

Automated external defibrillators (AEDs) can be used to identify and promptly terminate ventricular fibrillation and ventricular tachycardia in patients with sudden cardiac arrest (SCA). They may thereby allow bystanders to administer potentially life-saving therapy critical minutes earlier than can be accomplished by emergency medical personnel. As a consequence, AEDs are increasingly being deployed in public places, such as airports and shopping malls, and available evidence suggests that they do increase survival to hospital discharge following a SCA.^{1–4} However, the impact of public access AEDs on overall morbidity and mortality following SCA is limited, as approximately seventy-five percent of out-of-hospital SCAs occur in the home.^{1,5}

We conducted the Home Automatic External Defibrillator Trial (HAT), an international, multicenter, randomized clinical trial, to compare the effect of placing an AED in the home versus no home AED in 7001 stable patients with a prior anterior myocardial infarction. Spouse/companions in both treatment groups were taught cardiopulmonary resuscitation (CPR) and instructed to call emergency medical services (EMS) promptly. As previously reported, home access to an AED had no significant effect on all-cause mortality.⁵

Previous studies on the psychosocial and other quality of life effects of home AEDs for patients and their spouse/companions have been small and inconclusive. In a randomized trial of 158 patients with a recent acute ischemic event, home AED access was associated with trends toward worse quality of life on most subscales of the Short Form-36, particularly for social functioning.⁶ Two smaller interview studies with patients and their spouse/companions suggested that access to a home AED improved feelings of security and control.^{7,8} We examined the quality of life effects of home access to AEDs in a randomly selected subset of patients and their spouse/companions enrolled in HAT.

METHODS

Patient Population and Study Overview

Between January 23, 2003 and October 20, 2005, 7001 clinically stable patients with a history of anterior wall Q-wave or non-Q-wave myocardial infarction and who had a spouse or companion who was willing and able to call EMS, perform CPR, and use an AED were enrolled.^{5,9} Patients were recruited from sites in the United States, Canada, United Kingdom, Australia, New Zealand, Ireland, Germany and the Netherlands and were randomly assigned to receive an AED for home use or no AED. All spouses/companions of patients in the trial were trained to promptly call EMS and perform CPR, and those randomized to the home AED were also trained to use the device and instructed to do so prior to calling emergency services and starting resuscitation if SCA occurred. Details of the methods used to train the spouse/companion and complete inclusion and exclusion criteria have been previously published.^{5,9} The primary

endpoint of the study was all-cause mortality. No overall survival advantage was observed for the home AED arm over a mean follow-up of 37.3 months.⁵

Quality of life was a prespecified secondary endpoint of the HAT trial.

Funding of Quality of Life Study and Human Subjects Protection

The HAT trial was funded by grant U01 HL67972 from the National Heart, Lung, and Blood Institute. Additional funding came from Philips Medical Systems and Laerdal Medical as a subsidiary distributor. The corporate sponsors were not involved in trial design, data collection or analysis, or manuscript preparation. All patients and spouse/companions provided informed consent and the study protocol was approved by each site's institutional review board or ethics committee. The authors had complete independence in the conduct of the analyses, interpretation of the data, and preparation of this paper and are solely responsible for its content.

Quality of Life Data Collection Methods

Of the 7001 patients and their spouse/companions, 1007 (14%) were selected for the QOL assessment using permuted block randomization designed to balance the number of patients selected from each of the HAT treatment arms within each clinical site. Germany (14 patients enrolled in HAT) and the Netherlands (2 patients enrolled) did not participate in the QOL study. A random sample was used for the QOL portion of HAT for budgetary reasons and because it was projected that there would be >80% power to detect differences of one quarter of a standard deviation (SD) or greater in the SF-36 scales with >700 patients. Selected patients and their spouse/companions participated in a structured QOL interview at baseline and then at 12 and 24 months post-randomization. Patients and spouses/companions were interviewed separately by each site's study coordinators. Overall collection of QOL data was coordinated by the Seattle Institute for Cardiac Research, with support during follow-up from the Duke Clinical Research Institute (DCRI). Data were transferred to the DCRI for analyses.

Quality of Life Measures for Patients

Only limited data were available regarding the QOL effects of home AED therapy to guide the selection of a primary QOL measure when HAT was designed. However, related work on the effects of CPR training suggested that psychological distress/well-being was the QOL domain most likely to demonstrate an effect, should one be present. The QOL battery used for patients in HAT consisted of 4 instruments:

1. The Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). We used the SF-36 Mental Health Inventory-5 (MHI-5) as measurement of anxiety/depression symptoms and the 4-item vitality subscale from the SF-36 for energy/fatigue. Both sub-scales were scored from 0–100, with higher scores representing better psychological well-being and more energy. A change of 5 points or greater is considered clinically significant. The MHI-5 has shown excellent validity against more comprehensive measures of anxiety and depression.¹⁰ We used the remaining six subscales from the SF-36 to assess general health, physical function, role functioning-physical, role functioning-emotional, social functioning, and bodily pain. In addition, we calculated the two summary scores for the SF-36 covering physical and mental health.¹¹ The Physical Health summary scale is a composite of the SF-36 physical functioning, role-physical, bodily pain, and general health subscales. The SF-36 Mental Health summary scale is a composite of the SF-36 vitality, social functioning, role-emotional, and mental health subscales. For the two summary scales, we report results using the more recently devised scoring method in which the standard 0–100 scores are transformed to a norm-based score where the reference score has a mean of 50 and a standard deviation of 10. There are no official standards

for what constitutes a clinically significant difference in the SF-36 scores. To facilitate interpretation, we have used a one-quarter standard deviation difference between groups as the benchmark for the minimum clinically significant difference (corresponding to approximately 2.5 points for the summary scales and 5 points for the others).^{12,13}

2. The Influential Relationships Questionnaire (IRQ): This is a 37-item measure that assesses perceptions of three aspects of interpersonal relationships: care, overprotection, and criticism.¹⁴ Higher scores indicate less caring, more overprotection, and more criticism. Defining a clinically significant difference as one quarter of a SD translates to 1.5 points on the IRQ scales.
3. We used a modification of a questionnaire developed by Dracup and colleagues to examine how reassured patients felt knowing that CPR or an AED would be used if needed.¹⁵
4. The EuroQoL-5D (EQ-5D) consists of two parts: a) a visual analog scale self-rated measure of generic health status where 0 represents the worst imaginable and 100 the best imaginable health state and b) the EQ-5D index, which summarizes and expresses the assessment of health status in five dimensions.^{16,17} The EQ-5D was collected on all 7001 HAT patients.

Quality of Life Measures for Spouses/Companions

Three sets of scales were collected from spouses/companions:

1. The SF-36 MHI-5 and the vitality subscales were used to assess psychological distress/well-being and energy/fatigue, respectively.
2. The Influential Relationships Questionnaire, described above.
3. Questions developed by Dracup and colleagues were used to examine attitudes of the spouse/companion toward the AED and CPR.¹⁵ These questions elicited overall feelings about the assigned intervention (CPR training/AED access), sense of responsibility attributed to the treatment assignment, anxiety about the prospect of using the treatment, and reassurance derived from the assigned treatment.

Statistical Analyses

As with the primary analyses of HAT, comparisons of QOL were undertaken on an intention-to-treat basis, so that the initial random treatment assignment was used to define the patient's treatment group regardless of subsequent management. Continuous or ordinal variable comparisons between groups used the Wilcoxon rank-sum test, and group comparisons of categorical variables used a chi-square test. Summary statistics for continuous variables are reported as medians with interquartile ranges or means with standard deviations. Discrete variables are summarized using frequencies and percentages. Treatment group comparisons with $p < 0.05$ were considered statistically significant.

RESULTS

Patient Population and Baseline Characteristics

Of the 1007 patients randomly selected for participation in the QOL substudy of HAT, 948 (94%) provided baseline QOL data and formed the study population (Figure 1). Baseline characteristics for the patients participating in the QOL assessment and their spouse/companions were quite similar to those of the overall HAT study cohort, indicating that the random selection process had accomplished its objective (Appendix Table A1). In addition, baseline characteristics of patients in the two treatment arms were well balanced (Table 1).

The median age of the QOL cohort was 62 years, 17% were female and 12% represented racial minorities. Median time from the qualifying anterior MI to enrollment was 2 years. Seventy-five percent had a history of previous coronary revascularization. Median ejection fraction among the 80% of patients in whom it was known was 45%. Sixty-five percent of patients were in New York Heart Association Class I and 30% were in Class II. Among spouse/companions, 89% were spouses, 4% were companions, and 7% were other (e.g., sibling, child), and median spouse/companion age was 58 years.

Quality of Life Outcomes for Patients

From a total of 2846 expected patient contacts, 2473 QOL questionnaires were collected, representing 94% of patients eligible for this assessment at baseline and 83% of those eligible at 1 and 2 years of follow-up (Figure 1). Follow-up for QOL was more complete in the AED arm at 1 year (87% of eligible provided data versus 79% of the CPR only arm) and 2 years (86% versus 81%) (Table 2). These differences in response rates were part of a pattern seen in the clinical follow-up of the entire trial.

The median MHI-5 score was 80 in both treatment groups at baseline, did not change during follow-up and did not differ in follow-up between treatment groups (all p values >0.10) (Table 3). At baseline, median vitality scores were 60 in the AED plus CPR arm and 65 in the CPR-only arm ($p=0.21$). At 1 and 2 years follow-up, median vitality scores were 60 in each treatment group and these did not differ by treatment (each $p>0.10$).

Secondary Quality of Life Comparisons for Patients—No clinically and statistically significant differences were found between groups for the SF-36 Physical Health and Mental Health summary scales or the SF-36 subscales for general health perceptions, physical functioning, role functioning-physical, role-functioning-emotional, and social functioning (Appendix Table A2). While two comparisons yielded p values <0.05 (SF-36 General Health Perceptions and SF-36 Physical Health Summary at 1 year), in neither case did the observed difference also meet criteria for a clinically significant difference (Appendix Table A2).

The Influential Relationships Questionnaire revealed no significant difference by treatment group in perceptions of the patients or their spouse/companions in the areas of caring, criticism, and overprotection. No differences by treatment group were found in the EQ-5D visual analog scale or single summary index.

At 12 months, 72% of the AED group versus 61% of the CPR-only group reported feeling “extremely” or “quite a bit” reassured knowing they would be treated with CPR/AED if needed ($p=0.0014$). At 24 months, these rates were 72% in the AED arm and 55% in the CPR-only group ($p<0.0001$) (Table 4).

Quality of Life Comparisons for Spouses/Companions

Among spouses/companions, no significant differences were found in the MHI-5, SF-36 vitality scale, or IRQ scores between groups with up to 2 years of follow-up (Appendix Table A3).

Spouses/companions assigned to the home AED group responded more positively toward to their assigned treatment mode than did spouses/companions who were instructed in using only CPR, with 88–89% of the AED group feeling “very positive” about learning their intervention compared with 81% of the CPR-only group ($p=0.0015$ at 12 months, $p=0.0073$ at 24 months) (Table 3). No significant differences were found between the groups in their response to the sense of responsibility placed on the spouse/companion from learning CPR or to use an AED. Spouses/companions in the home AED group reported less apprehension about the possibility

of using their assigned intervention than spouses/companions in the CPR-only group. At 1 year, 75% of the AED spouse/companions were “not at all” or only “a little bit” nervous about the possibility of using their assigned resuscitation mode if needed compared with 64% of the CPR-only group ($p=0.036$). Corresponding rates at 2 years were 72% and 61%, respectively ($p=0.026$).

DISCUSSION

Our study has 3 important findings. First, home placement of an AED for stable patients with a previous anterior MI did not impair psychological well-being or any other aspects of QOL in either the patients or their spouse/companions out to 2 years of follow-up. Secondly, home placement of an AED did not adversely affect the interpersonal relationship between patients and their spouse/companions compared with having CPR training only. Finally, home placement of an AED provided more reassurance to the patient than training the spouse/companion to perform CPR alone, and the additional responsibility did not increase spouse/companion anxiety.

The Home Automatic External Defibrillator Trial was the first large-scale randomized test of the hypothesis that providing home AED access to patients at increased risk for SCA could lower all-cause mortality. Previous studies have focused solely on cardiac arrest mortality. As reported previously, the trial did not demonstrate a survival benefit with home AED access, probably for several reasons.⁵ First, the mortality rate observed in HAT and the incidence of SCA were much lower than expected based on prior experience and the trial was thus underpowered. Second, although almost three-quarters of tachyarrhythmic SCAs occurred in the home, as expected, less than half were witnessed. Even in those witnessed in the AED arm, an AED was not always applied. While the home AED does save lives when used appropriately in a timely fashion and although there was no documented instance of an inappropriate shock, HAT shows that it is an inefficient means of addressing the important public health problem of SCA in the population and in the manner of implementation we selected.

Assessing the effects of a home AED on patient QOL differs from most clinical trial assessments of QOL, since placing an AED in the home of an at risk patient does not require anything specific to be done to the patient beyond some explanation and training of household members. An AED that is stored somewhere in the house and is rarely thought about would presumably have no more detectable effects on patient or spouse/companion QOL than a home fire extinguisher. A reasonable presumption, therefore, is that effects of the AED on QOL most likely would be mediated primarily through the explanations given by study personnel when the patients were randomized or the sense of dependency or responsibility inculcated in the participants. Prior to randomization, patients may not have been aware of their potential for SCA and finding out that their doctors felt that the risk was significant enough to consider participation in HAT could have induced a number of different psychological reactions. Similarly, the unblinded treatment assignment might have augmented or mitigated those reactions in different ways, depending on knowledge about cardiac arrests and their treatment, prior experience with CPR and AEDs, and individual personality factors. Since the effectiveness of home AED therapy is critically dependent on the spouse/companion, as well as patient factors, this therapy also has the potential to affect household interpersonal relationships more than most other therapies given to patients with coronary heart disease.

Prior to the HAT trial, there was very little empirical data relating to psychological or other QOL effects that home placement of an AED might generate. In a small study of post-myocardial infarction patients, interviews with patients and with spouse/companions suggested that access to an AED would enhance feelings of security and control and would neither increase patient stress or anxiety nor augment relationship stress.⁷ More recently, 158 patients

and family members with a recent acute ischemic cardiac event were randomly assigned to received CPR training with or without home AED access.⁶ QOL was assessed with the SF-36 at 2 weeks, 3 months, and 9 months and scores were worse in the AED arm on most scales at all follow-up points. However, most of the differences were not large enough to be considered clinically significant, and significant imbalances in some baseline scores combined with a small sample size made the results of the study inconclusive. Earlier studies of the psychological effects of CPR training on the patient and spouse/companion also suggested the potential for adverse consequences.¹⁸ In this context, our much larger study provides important reassurance that home access to an AED as implemented in the HAT trial does not cause a general increase in anxiety or feelings of social isolation relative to CPR training alone. Although the presence of an AED and what it signifies might cause patients to become dependent on the security of home and the presence of the spouse/companion, we did not see any evidence that patients in the AED arm or their spouses spent less time out of the home than the CPR subjects (data not shown). Neither did we observe any increase in stress between patients and their spouse/companions related to the interdependence created by the presence of the AED in the home.

Several caveats should be kept in mind when evaluating our results. First, our follow-up response rate for patients in the QOL portion of HAT was lower than expected (83%) and was better in the AED arm at 1 and 2 years. This may have led to undetected biases, although it seems unlikely that a clinically important difference in QOL was obscured by this follow-up difference. Secondly, the assigned study intervention was not masked, and patient and spouse/companion biases about CPR and about AEDs may have influenced our findings. Third, we did not have sufficient numbers of patient/spouse pairs with a SCA event in the QOL subset to examine the effects of the intervention on spouse/companion post-event QOL and attitudes. Finally, two countries (Germany and the Netherlands) entered HAT late (16 patients total enrollment) and were not included in the QOL portion of the study, in part due to the added expense of obtaining valid translations of the study instruments for those countries.

In conclusion, placement of an AED in the home of patients at increased risk for SCA due to a prior anterior myocardial infarction did not affect quality of life either for them or their spouse/companion but did provide more reassurance to patients without increasing anxiety for spouse/companions compared with CPR training alone.

Acknowledgments

We thank Diane Minshall-Liu for additional follow-up QOL coordination and site management and Melanie R. Daniels for editing this manuscript. We are also greatly indebted to the site coordinators at each of the participating HAT sites who enrolled and followed the study patients. Finally, we thank the participating patients and spouse/companions who agreed to be a part of this study.

FUNDING SOURCES

Supported by grant (U01 HL67972) from the National Heart, Lung, and Blood Institute/National Institutes of Health, Bethesda, MD. Additional funding came from Philips Medical Systems and Laerdal Medical as a subsidiary distributor.

Supported by grant (U01 HL67972) from the National Heart, Lung, and Blood Institute/National Institutes of Health, Bethesda, MD.

References

1. Hallstrom AP, Ornato JP, Weisfeldt M, Travers A, Christenson J, McBurnie MA, Zalenski R, Becker LB, Schron EB, Proschan M. Public-access defibrillation and survival after out-of-hospital cardiac arrest. *N Engl J Med* 2004;351:637–46. [PubMed: 15306665]
2. Page RL, Joglar JA, Kowal RC, Zagrodzky JD, Nelson LL, Ramaswamy K, Barbera SJ, Hamdan MH, McKenas DK. Use of automated external defibrillators by a U.S. airline. *N Engl J Med* 2000;343:1210–6. [PubMed: 11071671]

3. Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. *N Engl J Med* 2000;343:1206–9. [PubMed: 11071670]
4. Caffrey SL, Willoughby PJ, Pepe PE, Becker LB. Public use of automated external defibrillators. *N Engl J Med* 2002;347:1242–7. [PubMed: 12393821]
5. Bardy GH, Lee KL, Mark DB, Poole JE, Toff WD, Tonkin AM, Smith W, Dorian P, Packer DL, White RD, Longstreth WT Jr, Anderson J, Johnson G, Bischoff E, Yallop JJ, McNulty S, Ray LD, Clapp-Channing NE, Rosenberg Y, Schron EB. Home use of automated external defibrillators for sudden cardiac arrest. *N Engl J Med* 2008;358:1793–804. [PubMed: 18381485]
6. Cagle AJ, Diehr P, Meischke H, Rea T, Olsen J, Rodrigues D, Yakovlevitch M, Amidon T, Eisenberg M. Psychological and social impacts of automated external defibrillators (AEDs) in the home. *Resuscitation* 2007;74:432–8. [PubMed: 17395358]
7. Chen MA, Eisenberg MS, Meischke H. Impact of in-home defibrillators on postmyocardial infarction patients and their significant others: an interview study. *Heart Lung* 2002;31:173–85. [PubMed: 12011808]
8. Haugk M, Robak O, Sterz F, Uray T, Kliegel A, Losert H, Holzer M, Herkner H, Laggner AN, Domanovits H. High acceptance of a home AED programme by survivors of sudden cardiac arrest and their families. *Resuscitation* 2006;70:263–74. [PubMed: 16828958]
9. Bardy GH, Lee KL, Mark DB, Poole JE, Toff WD, Tonkin AM, Smith W, Dorian P, Yallop JJ, Packer DL, White RD, Longstreth W, Anderson J, Johnson G, Bischoff E, Munkers CD, Brown A, McNulty S, Ray LD, Clapp-Channing NE, Rosenberg Y, Salive M, Schron EB. Rationale and design of the Home Automatic External Defibrillator Trial (HAT). *Am Heart J* 2008;155:445–54. [PubMed: 18294476]
10. Berwick DM, Murphy JM, Goldman PA, Ware JE Jr, Barsky AJ, Weinstein MC. Performance of a five-item mental health screening test. *Med Care* 1991;29:169–76. [PubMed: 1994148]
11. Ware JE, Kosinski M. Interpreting SF-36 summary health measures: a response. *Qual Life Res* 2001;10:405–13. [PubMed: 11763203]
12. Mark DB, Anstrom KJ, Sun JL, Clapp-Channing NE, Tsiatis AA, Davidson-Ray L, Lee KL, Bardy GH. Quality of life with defibrillator therapy or amiodarone in heart failure. *N Engl J Med* 2008;359:999–1008. [PubMed: 18768943]
13. Mark DB, Pan W, Clapp-Channing NE, Anstrom KJ, Ross JR, Fox RS, Devlin GP, Martin CE, Adlbrecht C, Cowper PA, Ray LD, Cohen EA, Lamas GA, Hochman JS. Quality of life after late invasive therapy for occluded arteries. *N Engl J Med* 2009;360:774–83. [PubMed: 19228620]
14. Baker B, Kazarian S, Marquez-Julio A. Perceived interpersonal attitudes and psychiatric complaints in patients with essential hypertension. *J Clin Psychol* 1994;50:320–4. [PubMed: 8071437]
15. Dracup K, Moser DK, Guzy PM, Taylor SE, Marsden C. Is cardiopulmonary resuscitation training deleterious for family members of cardiac patients? *Am J Public Health* 1994;84:116–8. [PubMed: 8279597]
16. The EuroQol Group. EuroQol--a new facility for the measurement of health-related quality of life. *Health Policy* 1990;16:199–208. [PubMed: 10109801]
17. Rosser, RM.; Stintonen, H. The EuroQoL quality of life project. In: Walker, SR.; Rosser, RM., editors. *Quality of Life Assessment: Key Issues in the 1990s*. Dordrecht: Kluwer Academic Publishers; 1993. p. 197-9.
18. Dracup K, Moser DK, Taylor SE, Guzy PM. The psychological consequences of cardiopulmonary resuscitation training for family members of patients at risk for sudden death. *Am J Public Health* 1997;87:1434–9. [PubMed: 9314793]

Figure 1.
Data collection rates in the HAT QOL substudy.

Table 1**Baseline Characteristics by Intention to Treat**

	EMS Call/CPR (n=473)	AED + EMS Call/CPR (n=475)
Patients		
Age, years median (interquartile range)	62 (54, 70)	62 (55, 69)
Female	18% (86)	16% (76)
Racial or ethnic minority	15% (70)	9% (44)
Time since most recent anterior MI		
≤1 Month	10% (39)	12% (48)
>1 Month to 3 months	10% (42)	7% (30)
>3 Months to 6 months	9% (38)	10% (42)
>6 Months to 1 year	9% (38)	10% (42)
>1 Year	62% (252)	61% (257)
Employment Status		
Full time	33% (157)	31% (145)
Part time	8% (38)	14% (66)
Not employed	59% (252)	56% (264)
Estimated daily time alone at home – hr median (interquartile range)	1.1 (0.3, 4.0)	2.0 (0.5, 4.0)
Estimated daily time away from home – hr median (interquartile range)	3.5 (2.0, 8.0)	3.5 (2.0, 7.0)
Previous procedures - % (no.)		
Percutaneous coronary revascularization	57% (269)	54% (257)
Coronary artery bypass grafting	26% (125)	28% (132)
Coexisting conditions - % (no.)		
Hypertension	54% (255)	51% (241)
Diabetes	22% (105)	21% (101)
Hypercholesterolemia	72% (387)	79% (375)
Stroke	6% (30)	8% (36)
Ejection fraction measured – % (no.)	82% (386)	79% (377)
Left ventricular ejection fraction - % median (interquartile range)	48 (38, 59)	45 (37, 53)
Body mass index – kg.m ⁻² median (interquartile range)	27.5 (25.2, 30.9)	27.7 (25.3, 30.7)
NYHA Class – % (no.)		
I	67% (318)	62% (296)
II	28% (132)	32% (150)
III	5% (23)	6% (29)
Type of myocardial infarction – % (no.)		
Anterior Q-wave	63% (299)	69% (326)
Anterior non-Q-wave	37% (174)	31% (149)
Use of medication – % (no.)		
Beta-blocker (other than sotalol or amiodarone)	80% (381)	80% (378)
ACE inhibitor or angiotensin-receptor blocker	81% (384)	80% (381)
Statin	89% (422)	89% (422)
Daily use of aspirin	87% (412)	86% (411)
Digoxin	7% (31)	6% (29)

	EMS Call/CPR (n=473)	AED + EMS Call/CPR (n=475)
Warfarin	15% (72)	20% (97)
Any antiarrhythmic drug	4% (17)	6% (30)
Spouse or companion		
Relationship to patient – % (no.)		
Spouse	88% (416)	90% (428)
Companion	5% (26)	3% (14)
Other	7% (31)	7% (33)
Age – yr median (interquartile range)	58 (49, 66)	59 (50, 66)
Employment Status – % (no.)		
Full time	32% (153)	30% (142)
Part time	15% (70)	17% (79)
Not employed	53% (250)	54% (254)
Estimated daily time away from home – hr median (interquartile range)	3.0 (2.0, 7.0)	3.0 (2.0, 7.0)
Completed secondary school – % (no.)	82% (389)	82% (390)

Table 2

Collection of QOL Data by Treatment Group Over the 2-Year Follow-up

	All	EMS Call/CPR	AED + EMS Call/CPR
Patients enrolled in HAT	7001	3506	3495
Randomized to QOL	1007 (14%)	507 (14%)	500 (14%)
Provided Baseline responses	948 (94%)	473 (93%)	475 (95%)
Excluded between Baseline and Year 1	20 (2%)	14 (3%)	6 (1%)
died	15	9	6
withdrew consent	5	5	0
Eligible for Year 1	928 (98%)	459 (97%)	469 (99%)
Provided Year 1 responses	768 (83%)	362 (79%)	406 (87%)
Excluded between Year 1 and Year 2	17 (2%)	7 (2%)	10 (2%)
died	10	3	7
withdrew consent	7	4	3
Eligible for Year 2	911 (98%)	452 (98%)	459 (98%)
Provided Year 2 responses	757 (83%)	364 (81%)	393 (86%)

Table 3**Primary HAT Quality of Life Measures – Patients**

	EMS Call/CPR	AED + EMS Call/CPR	P-value
MOS SF 36 Mental Health Inventory 5			
Baseline			0.38
N	452	459	
Median (25th, 75th)	80.0(65.0, 88.0)	80.0(68.0, 88.0)	
Mean ± SD	75.7 ± 16.9	76.9 ± 15.7	
Year 1			0.55
N	355	393	
Median (25th, 75th)	80.0(68.0, 92.0)	80.0(68.0, 88.0)	
Mean ± SD	76.7 ± 17.1	76.7 ± 15.5	
Year 2			0.96
N	347	383	
Median (25th, 75th)	80.0(64.0, 88.0)	80.0(64.0, 88.0)	
Mean ± SD	75.4 ± 17.7	75.7 ± 16.6	
MOS SF 36 Vitality Scale			
Baseline			0.21
N	457	463	
Median (25th, 75th)	65.0(50.0, 75.0)	60.0(45.0, 75.0)	
Mean ± SD	60.4 ± 20.5	58.9 ± 20.5	
Year 1			0.19
N	357	396	
Median (25th, 75th)	60.0(50.0, 75.0)	60.0(45.0, 75.0)	
Mean ± SD	59.7 ± 21.3	58.5 ± 19.9	
Year 2			0.98
N	353	385	
Median (25th, 75th)	60.0(50.0, 75.0)	60.0(50.0, 75.0)	
Mean ± SD	58.9 ± 21.0	59.0 ± 20.1	
EQ-5D Visual Analog Scale			
0–100 scale; 0=worst imaginable health, 100=perfect health			
Baseline			
No. of patients	504	499	0.13
Median (interquartile range)	80.0 (70.0, 90.0)	80.0 (70.0, 85.0)	
Mean ± standard deviation	76.2 ± 16.2	74.9 ± 16.4	
Year 1			
No. of patients	451	463	0.25
Median (interquartile range)	80.0 (70.0, 90.0)	80.0 (70.0, 90.0)	
Mean ± standard deviation	78.2 ± 17.0	77.5 ± 16.3	
Year 2			
No. of patients	415	426	0.37
Median (interquartile range)	80.0 (70.0, 90.0)	80.0 (70.0, 90.0)	
Mean ± standard deviation	77.9 ± 16.3	77.1 ± 15.9	

	EMS Call/CPR	AED + EMS Call/CPR	P-value
EQ-5D Single Summary Index (Health State)			
Baseline			
No. of patients	504	499	0.20
Median (interquartile range)	0.87 (0.73, 1.00)	1.00 (0.78, 1.00)	
Mean ± standard deviation	0.83 ± 0.22	0.86 ± 0.19	
Year 1			
No. of patients	450	466	0.50
Median (interquartile range)	1.00 (0.73, 1.00)	0.85 (0.73, 1.00)	
Mean ± standard deviation	0.84 ± 0.23	0.84 ± 0.21	
Year 2			
No. of patients	422	434	0.36
Median (interquartile range)	0.85 (0.73, 1.00)	1.00 (0.74, 1.00)	
Mean ± standard deviation	0.82 ± 0.25	0.85 ± 0.20	

Table 4**Patient and Spouse/Companion Attitudes about CPR/AED**

	EMS Call/CPR	AED + EMS Call/CPR	P-value
Patient			
CPR/AED Attitude: How reassured are you knowing that you will be treated with CPR/AED if needed?			
Baseline			<0.0001
N	449	462	
Not at all	8% (37)	6% (29)	
A little bit	9% (42)	7% (32)	
Moderately	21% (94)	11% (50)	
Quite a bit	33% (149)	38% (177)	
Extremely	28% (127)	38% (174)	
Year 1			0.0014
N	352	392	
Not at all	7% (24)	7% (27)	
A little bit	11% (37)	6% (25)	
Moderately	21% (75)	15% (59)	
Quite a bit	37% (130)	35% (136)	
Extremely	24% (86)	37% (145)	
Year 2			<0.0001
N	348	380	
Not at all	7% (26)	8% (31)	
A little bit	11% (40)	6% (24)	
Moderately	26% (89)	13% (51)	
Quite a bit	29% (101)	35% (133)	
Extremely	26% (92)	37% (141)	
Spouse/Companion			
CPR/AED:			
What are your feelings about learning [CPR/AED]?			
Baseline			
N	456	468	0.40*
Very positive	91.2% (416)	93.4% (437)	
Ambivalent	8.6% (39)	6.2% (29)	
Negative/Very negative (<i>combined due to small cell sizes</i>)	0.2% (1)	0.4% (2)	
Year 1			
N	345	383	0.0015*
Very positive	80.6% (278)	88.3% (338)	
Ambivalent	18.8% (65)	10.2% (39)	
Negative/Very negative (<i>combined due to small cell sizes</i>)	0.6% (2)	1.6% (6)	
Year 2			
N	328	363	0.0073*
Very positive	80.5% (264)	88.7% (322)	
Ambivalent	18.0% (59)	10.7% (39)	

	EMS Call/CPR	AED + EMS Call/CPR	P-value
Negative/Very negative <i>(combined due to small cell sizes)</i>	1.5% (5)	0.6% (2)	
CPR/AED:			
What is your sense of the responsibility placed on you by learning [CPR/AED]?			
Baseline			
N	455	468	0.16
Too much	3.3% (15)	2.8% (13)	
Right amount	86.8% (395)	90.0% (421)	
Very little	4.8% (22)	4.9% (23)	
None	5.1% (23)	2.4% (11)	
Year 1			
N	344	379	0.58
Too much	5.2% (18)	3.4% (13)	
Right amount	86.1% (296)	87.1% (330)	
Very little	5.8% (20)	5.5% (22)	
None	2.9% (10)	4.0% (15)	
Year 2			
N	332	365	0.57
Too much	4.5% (15)	4.4% (16)	
Right amount	84.0% (279)	87.1% (318)	
Very little	8.4% (28)	5.8% (21)	
None	3.0% (10)	2.7% (10)	
How nervous are you about the possibility of using [CPR/AED] if needed?			
Baseline			
N	458	471	0.32
Not at all	23.4% (107)	23.8% (112)	
A little bit	47.4% (217)	52.4% (247)	
Moderately	17.7% (81)	15.5% (73)	
Quite a bit	9.6% (44)	7.2% (34)	
Extremely	2.0% (9)	1.1% (5)	
Year 1			
N	346	383	0.0357
Not at all	18.5% (64)	21.4% (82)	
A little bit	45.7% (158)	53.3% (204)	
Moderately	21.1% (73)	15.7% (60)	
Quite a bit	12.1% (42)	7.3% (28)	
Extremely	2.6% (9)	2.4% (9)	
Year 2			
N	334	367	0.0258
Not at all	18.6% (62)	20.2% (74)	
A little bit	42.2% (141)	51.8% (190)	
Moderately	24.6% (82)	16.4% (60)	
Quite a bit	11.1% (37)	9.5% (35)	

	EMS Call/CPR	AED + EMS Call/CPR	P-value
Extremely	3.6% (12)	2.2% (8)	

Continuous variable p-values are based on Wilcoxon Signed-rank test. Categorical variable p-values are based on Likelihood Ratio Chi-Square, except for those indicated with (*) which used Fishers Exact test.

Appendix Table A1

Baseline Characteristics of Overall HAT Patient Population versus Quality of Life Subset

	Overall HAT (n=7001)	HAT QOL Substudy* (n=948)
Patients		
Age, years median (interquartile range)	62 (54, 70)	62 (54, 70)
Female	17% (1220)	17% (162)
Racial or ethnic minority	13% (906)	12% (114)
Time since most recent anterior MI		
≤1 Month	10% (566)	11% (87)
>1 Month to 3 months	10% (590)	9% (72)
>3 Months to 6 months	9% (554)	9% (78)
>6 Months to 1 year	11% (670)	10% (80)
>1 Year	60% (3578)	62% (509)
Employment Status		
Full time	33% (2284)	32% (302)
Part time	10% (697)	11% (104)
Not employed	57% (4020)	57% (542)
Estimated daily time alone at home – hr median (interquartile range)	1.5 (0.5, 4.0)	1.5 (0.5, 4.0)
Estimated daily time away from home – hr median (interquartile range)	4.0 (2.0, 8.0)	3.5 (2.0, 7.5)
Previous procedures - no. (%)		
Percutaneous coronary revascularization	53% (3742)	55% (526)
Coronary artery bypass grafting	27% (1867)	27% (257)
Coexisting conditions - no. (%)		
Hypertension	54% (3769)	52% (496)
Diabetes	21% (1504)	22% (206)
Hypercholesterolemia	79% (5557)	80% (762)
Stroke	6% (437)	7% (66)
Ejection fraction measured – % (no.)	80% (5624)	80% (763)
Left ventricular ejection fraction - % median (interquartile range)	45 (35, 55)	45 (37, 55)
Body mass index – kg.m ⁻² median (interquartile range)	27.7 (25.0, 30.9)	27.7 (25.3, 30.7)
NYHA Class – no. (%)		
I	65% (4570)	65% (614)
II	29% (2053)	30% (282)
III	5% (367)	5% (52)
IV	<1% (11)	0% (0)
Type of myocardial infarction – no (%)		
Anterior Q-wave	64% (4509)	66% (625)
Anterior non-Q-wave	36% (2491)	34% (323)
Use of medication – no. (%)		
Beta-blocker (other than sotalol or amiodarone)	79% (5531)	80% (759)
ACE inhibitor or angiotensin-receptor blocker	82% (5719)	81% (765)
Statin	89% (6241)	89% (844)

	Overall HAT (n=7001)	HAT QOL Substudy* (n=948)
Daily use of aspirin	87% (6063)	87% (823)
Digoxin	7% (489)	6% (60)
Warfarin	18% (1249)	18% (169)
Any antiarrhythmic drug	4% (298)	5% (47)
Spouse or companion		
Relationship to patient – no. (%)		
Spouse	88% (6150)	89% (844)
Companion	4% (303)	4% (40)
Other	8% (548)	7% (64)
Age – yr median (interquartile range)	58 (50, 66)	58 (50, 66)
Employment Status – no. (%)		
Full time	32% (2223)	31% (295)
Part time	17% (1196)	16% (149)
Not employed	51% (3582)	53% (504)
Estimated daily time away from home – hr median (interquartile range)	4.0 (2.0, 7.5)	3.0 (2.0, 7.0)
Completed secondary school – no. (%)	81% (5682)	82% (779)

* Defined as any QOL substudy-randomized patient that did not refuse to complete at least one of the two patient-oriented questionnaires at baseline

Appendix Table A2

Secondary Quality of Life Measures by Intention to Treat - Patient

	EMS Call/CPR	AED + EMS Call/CPR	P-value *
MOS Short Form-36 Subscales			
General Health Perceptions			
Baseline			0.21
N	457	461	
Median (25th, 75th)	65.0(47.0, 80.0)	62.0(45.0, 77.0)	
Mean $\pm$ SD	62.5 $\pm$ 21.8	60.7 $\pm$ 21.9	
Year 1			0.025
N	353	390	
Median (25th, 75th)	67.0(52.0, 80.0)	64.0(45.0, 77.0)	
Mean $\pm$ SD	64.3 $\pm$ 21.8	60.6 $\pm$ 22.6	
Year 2			0.52
N	342	381	
Median (25th, 75th)	67.0(50.0, 77.0)	62.0(47.0, 80.0)	
Mean $\pm$ SD	62.6 $\pm$ 21.4	61.4 $\pm$ 22.5	
Physical Functioning			
Baseline			0.19
N	464	469	
Median (25th, 75th)	80.0(55.0, 95.0)	75.0(50.0, 90.0)	
Mean $\pm$ SD	70.4 $\pm$ 26.5	68.1 $\pm$ 27.4	
Year 1			0.06
N	356	393	
Median (25th, 75th)	80.0(58.0, 95.0)	80.0(50.0, 90.0)	
Mean $\pm$ SD	72.3 $\pm$ 27.4	69.8 $\pm$ 26.1	
Year 2			0.13
N	354	388	
Median (25th, 75th)	80.0(50.0, 95.0)	75.0(50.0, 90.0)	
Mean $\pm$ SD	71.3 $\pm$ 26.8	68.8 $\pm$ 27.6	
Role Functioning - Physical			
Baseline			0.90
N	424	437	
Median (25th, 75th)	75.0(0.0, 100.0)	75.0(0.0, 100.0)	
Mean $\pm$ SD	57.4 $\pm$ 41.6	57.3 $\pm$ 41.7	
Year 1			0.48
N	343	384	
Median (25th, 75th)	75.0(25.0, 100.0)	75.0(25.0, 100.0)	
Mean $\pm$ SD	67.1 $\pm$ 39.2	64.8 $\pm$ 39.8	
Year 2			0.93
N	335	378	
Median (25th, 75th)	75.0(25.0, 100.0)	100.0(25.0, 100.0)	

	EMS Call/CPR	AED + EMS Call/CPR	P-value*
Mean $\pm$ SD	65.5 $\pm$ 39.8	65.5 $\pm$ 40.9	
Role Functioning - Emotional			
Baseline			0.52
N	422	425	
Median (25th, 75th)	100.0(67.0, 100.0)	100.0(67.0, 100.0)	
Mean $\pm$ SD	79.0 $\pm$ 35.0	77.4 $\pm$ 36.1	
Year 1			0.58
N	336	381	
Median (25th, 75th)	100.0(67.0, 100.0)	100.0(67.0, 100.0)	
Mean $\pm$ SD	82.2 $\pm$ 32.7	80.1 $\pm$ 34.7	
Year 2			0.93
N	331	376	
Median (25th, 75th)	100.0(67.0, 100.0)	100.0(67.0, 100.0)	
Mean $\pm$ SD	80.7 $\pm$ 34.9	82.2 $\pm$ 31.9	
Social Functioning			
Baseline			0.92
N	469	471	
Median (25th, 75th)	88.0(63.0, 100.0)	88.0(63.0, 100.0)	
Mean $\pm$ SD	77.7 $\pm$ 25.3	77.5 $\pm$ 25.9	
Year 1			0.78
N	357	397	
Median (25th, 75th)	88.0(63.0, 100.0)	88.0(63.0, 100.0)	
Mean $\pm$ SD	79.9 $\pm$ 25.2	80.0 $\pm$ 23.5	
Year 2			0.64
N	355	392	
Median (25th, 75th)	88.0(63.0, 100.0)	88.0(63.0, 100.0)	
Mean $\pm$ SD	79.2 $\pm$ 24.9	78.8 $\pm$ 24.2	
Bodily Pain			
Baseline			0.92
N	469	471	
Median (25th, 75th)	74.0(51.0, 100.0)	72.0(51.0, 100.0)	
Mean $\pm$ SD	68.9 $\pm$ 26.1	68.8 $\pm$ 25.9	
Year 1			0.37
N	357	397	
Median (25th, 75th)	74.0(52.0, 100.0)	74.0(51.0, 100.0)	
Mean $\pm$ SD	71.8 $\pm$ 26.7	70.9 $\pm$ 24.6	
Year 2			0.90
N	356	392	
Median (25th, 75th)	74.0(51.0, 100.0)	74.0(51.0, 100.0)	
Mean $\pm$ SD	70.7 $\pm$ 25.4	70.2 $\pm$ 26.1	

SF-36 Summary Scales

Physical Health Summary Scale

	EMS Call/CPR	AED + EMS Call/CPR	P-value*
Baseline			0.60
N	393	407	
Median (25th, 75th)	46.7(36.9, 53.6)	46.3(36.1, 53.5)	
Mean $\pm$ SD	44.8 $\pm$ 10.8	44.4 $\pm$ 11.1	
Year 1			0.037
N	325	364	
Median (25th, 75th)	49.6(40.2, 55.5)	47.6(36.7, 54.1)	
Mean $\pm$ SD	46.8 $\pm$ 10.9	45.3 $\pm$ 10.9	
Year 2			0.36
N	305	356	
Median (25th, 75th)	48.6(38.9, 55.0)	47.8(37.4, 54.2)	
Mean $\pm$ SD	46.2 $\pm$ 10.4	45.2 $\pm$ 11.4	
Mental Health Summary Scale			
Baseline			0.78
N	393	407	
Median (25th, 75th)	53.6(47.2, 57.7)	53.7(46.7, 57.9)	
Mean $\pm$ SD	51.3 $\pm$ 9.0	51.4 $\pm$ 9.0	
Year 1			0.73
N	325	364	
Median (25th, 75th)	54.0(47.8, 58.1)	53.8(47.1, 57.7)	
Mean $\pm$ SD	51.8 $\pm$ 8.7	51.7 $\pm$ 8.3	
Year 2			0.86
N	305	356	
Median (25th, 75th)	54.3(47.1, 58.0)	53.6(47.3, 57.8)	
Mean $\pm$ SD	51.2 $\pm$ 9.5	51.7 $\pm$ 8.6	
Reported Health Transition			
Baseline			0.09
N	467	469	
Much better than one year ago	13% (60)	10% (47)	
Somewhat better than one year ago	16% (75)	20% (95)	
About the same as than one year ago	43% (203)	46% (217)	
Somewhat worse than one year ago	22% (103)	17% (79)	
Much worse than one year ago	6% (26)	7% (31)	
Year 1			0.39
N	356	395	
Much better than one year ago	17% (60)	15% (61)	
Somewhat better than one year ago	22% (80)	26% (104)	
About the same as than one year ago	48% (172)	49% (195)	

	EMS Call/CPR	AED + EMS Call/CPR	P-value [*]
Somewhat worse than one year ago	11% (40)	8% (30)	0.20
Much worse than one year ago	1% (4)	1% (5)	
Year 2			
N	355	391	
Much better than one year ago	7% (25)	10% (41)	
Somewhat better than one year ago	19% (68)	21% (83)	
About the same as than one year ago	60% (213)	58% (225)	
Somewhat worse than one year ago	12% (43)	8% (33)	
Much worse than one year ago	2% (6)	2% (9)	
Influential Relationships Questionnaire			
Care			
Baseline			0.20
N	443	445	
Median (25th, 75th)	9.0(5.0, 12.0)	9.0(4.0, 12.0)	
Mean ± SD	9.0 ± 5.3	8.5 ± 5.3	
Year 1			0.85
N	345	385	
Median (25th, 75th)	10.0(5.0, 12.0)	10.0(4.0, 12.0)	
Mean ± SD	9.0 ± 5.8	8.9 ± 5.4	
Year 2			0.42
N	329	363	
Median (25th, 75th)	10.0(4.0, 12.0)	9.0(4.0, 12.0)	
Mean ± SD	9.1 ± 5.7	8.7 ± 5.5	
Criticism			
Baseline			0.42
N	438	440	
Median (25th, 75th)	10.0(5.0, 13.0)	9.5(4.0, 13.0)	
Mean ± SD	9.4 ± 5.6	9.0 ± 5.5	
Year 1			0.86
N	344	382	
Median (25th, 75th)	10.0(4.0, 13.0)	10.0(4.0, 13.0)	
Mean ± SD	9.0 ± 5.5	9.0 ± 5.5	
Year 2			0.31
N	325	362	
Median (25th, 75th)	10.0(4.0, 13.0)	9.0(4.0, 13.0)	
Mean ± SD	9.1 ± 5.6	8.7 ± 5.8	
Overprotection			
Baseline			0.62

	EMS Call/CPR	AED + EMS Call/CPR	P-value*
N	438	442	
Median (25th, 75th)	12.0(7.0, 14.0)	11.5(7.0, 15.0)	
Mean $\pm$ SD	10.9 $\pm$ 5.3	10.7 $\pm$ 5.2	
Year 1			0.56
N	342	383	
Median (25th, 75th)	12.0(6.0, 14.0)	12.0(7.0, 15.0)	
Mean $\pm$ SD	10.6 $\pm$ 5.4	10.8 $\pm$ 5.5	
Year 2			0.74
N	328	362	
Median (25th, 75th)	12.0(6.0, 14.0)	11.0(7.0, 14.0)	
Mean $\pm$ SD	10.4 $\pm$ 5.5	10.4 $\pm$ 5.6	

* P-value for continuous variables is based on Wilcoxon Rank-Sum test. P-value for categorical variables is based on Chi-square test.

Continuous variables shown as median (25th to 75th percentiles).

Categorical variables are shown as percentages.

Means are shown with standard deviations.

Appendix Table A3**Quality of Life Measures by Intention to Treat – Spouse/Companion Responses**

	EMS Call/CPR	AED + EMS Call/CPR	P-value
MOS Short Form-36 Scales			
Mental Health Inventory 5			
Baseline			
N	453	464	0.84
Median (25th, 75th)	80.0 (68.0, 88.0)	80.0 (68.0, 88.0)	
Mean $\pm$ SD	76.6 $\pm$ 13.8	76.3 $\pm$ 14.0	
Year 1			
N	345	375	0.92
Median (25th, 75th)	80.0 (68.0, 88.0)	80.0 (68.0, 88.0)	
Mean $\pm$ SD	75.5 $\pm$ 14.8	75.2 $\pm$ 15.5	
Year 2			
N	327	360	0.24
Median (25th, 75th)	76.0 (68.0, 88.0)	80.0 (68.0, 88.0)	
Mean $\pm$ SD	74.8 $\pm$ 15.8	76.3 $\pm$ 14.9	
Vitality			
Baseline			
N	455	466	0.27
Median (25th, 75th)	70.0 (60.0, 80.0)	70.0 (55.0, 88.0)	
Mean $\pm$ SD	67.1 $\pm$ 16.6	65.7 $\pm$ 17.7	
Year 1			
N	346	376	0.46
Median (25th, 75th)	65.0 (55.0, 75.0)	65.0 (50.0, 75.0)	
Mean $\pm$ SD	63.5 $\pm$ 17.3	62.4 $\pm$ 18.0	
Year 2			
N	330	361	0.99
Median (25th, 75th)	65.0 (53.3, 75.0)	65.0 (50.0, 75.0)	
Mean $\pm$ SD	62.8 $\pm$ 17.6	62.7 $\pm$ 18.1	
Influential Relationships Questionnaire – without imputation			
Care			
Baseline			
N	398	414	0.41
Median (25th, 75th)	10.0 (6.0, 13.0)	10.0 (5.0, 13.0)	
Mean $\pm$ SD	9.9 $\pm$ 5.7	9.4 $\pm$ 5.4	
Year 1			
N	317	342	0.27
Median (25th, 75th)	11.0 (6.0, 13.0)	10.0 (6.0, 13.0)	
Mean $\pm$ SD	10.5 $\pm$ 5.9	10.0 $\pm$ 5.5	
Year 2			
N	291	326	0.27
Median (25th, 75th)	11.0 (6.0, 14.0)	11.0 (6.0, 13.0)	

	EMS Call/CPR	AED + EMS Call/CPR	P-value
Mean $\pm$ SD	10.6 $\pm$ 6.1	10.0 $\pm$ 5.8	
Criticism			
Baseline			
N	376	402	0.67
Median (25th, 75th)	10.0 (5.0, 13.0)	10.0 (4.0, 13.0)	
Mean $\pm$ SD	9.6 $\pm$ 5.5	9.3 $\pm$ 5.9	
Year 1			
N	309	336	0.15
Median (25th, 75th)	11.0 (5.0, 14.0)	10.0 (4.0, 13.0)	
Mean $\pm$ SD	10.1 $\pm$ 5.8	9.6 $\pm$ 6.0	
Year 2			
N	287	320	0.37
Median (25th, 75th)	11.0 (5.0, 14.0)	10.0 (4.0, 14.0)	
Mean $\pm$ SD	10.0 $\pm$ 6.0	9.6 $\pm$ 6.3	
Overprotection			
Baseline			
N	397	411	0.64
Median (25th, 75th)	11.0 (6.0, 14.0)	11.0 (6.0, 14.0)	
Mean $\pm$ SD	10.2 $\pm$ 5.6	10.0 $\pm$ 5.3	
Year 1			
N	315	338	0.52
Median (25th, 75th)	12.0 (6.0, 14.0)	12.0 (6.0, 14.0)	
Mean $\pm$ SD	10.7 $\pm$ 5.6	10.4 $\pm$ 5.9	
Year 2			
N	294	327	0.91
Median (25th, 75th)	11.0 (6.0, 14.0)	12.0 (5.0, 14.0)	
Mean $\pm$ SD	10.5 $\pm$ 6.0	10.3 $\pm$ 6.0	
Influential Relationships Questionnaire – with imputation			
Care			
Baseline			
N	440	456	0.57
Median (25th, 75th)	11.0 (6.0, 13.0)	10.0 (5.0, 13.0)	
Mean $\pm$ SD	10.0 $\pm$ 5.6	9.6 $\pm$ 5.5	
Year 1			
N	335	372	0.73
Median (25th, 75th)	11.0 (6.0, 14.0)	11.0 (7.0, 13.0)	
Mean $\pm$ SD	10.5 $\pm$ 5.9	10.3 $\pm$ 5.7	
Year 2			
N	310	347	0.17
Median (25th, 75th)	11.0 (7.0, 14.0)	11.0 (6.0, 13.0)	
Mean $\pm$ SD	10.8 $\pm$ 6.1	10.1 $\pm$ 5.9	
Criticism			

	EMS Call/CPR	AED + EMS Call/CPR	P-value
Baseline			
N	439	450	0.72
Median (25th, 75th)	11.0 (5.0, 13.0)	11.0 (4.0, 14.0)	
Mean ± SD	9.8 ± 5.6	9.6 ± 5.8	
Year 1			
N	337	372	0.46
Median (25th, 75th)	11.0 (6.0, 14.0)	11.0 (5.0, 14.0)	
Mean ± SD	10.2 ± 5.7	10.1 ± 6.2	
Year 2			
N	310	343	0.38
Median (25th, 75th)	11.0 (5.0, 14.0)	10.0 (4.0, 14.0)	
Mean ± SD	10.2 ± 6.1	9.7 ± 6.3	
Overprotection			
Baseline			
N	436	453	0.99
Median (25th, 75th)	11.0 (6.0, 14.0)	11.0 (6.0, 14.0)	
Mean ± SD	10.2 ± 5.6	10.2 ± 5.4	
Year 1			
N	335	368	0.57
Median (25th, 75th)	12.0 (6.0, 14.0)	12.0 (6.0, 14.0)	
Mean ± SD	10.8 ± 5.7	10.6 ± 6.1	
Year 2			
N	306	344	0.76
Median (25th, 75th)	11.0 (6.0, 14.0)	12.0 (5.5, 14.0)	
Mean ± SD	10.5 ± 5.9	10.3 ± 6.0	

Appendix Table A4

EuroQoL for Overall HAT Population by Intention to Treat

	EMS Call/CPR	AED + EMS Call/CPR	P-value
EuroQoL Visual Analog Scale			
0–100 scale; 0=worst imaginable health, 100=perfect health			
Baseline			
No. of patients	3496	3485	0.24
Median (interquartile range)	80.0 (70.0, 90.0)	80.0 (70.0, 90.0)	
Mean ± standard deviation	76.2 ± 15.9	75.6 ± 16.4	
Year 1			
No. of patients	3090	3229	0.39
Median (interquartile range)	80.0 (70.0, 90.0)	80.0 (70.0, 90.0)	
Mean ± standard deviation	78.1 ± 16.1	78.5 ± 15.7	
Year 2			
No. of patients	2840	3011	0.82
Median (interquartile range)	80.0 (70.0, 90.0)	80.0 (70.0, 90.0)	
Mean ± standard deviation	78.0 ± 16.1	78.0 ± 16.4	
EuroQoL Single Summary Index (Health State)			
Baseline			
No. of patients	3491	3478	0.82
Median (interquartile range)	0.88 (0.73, 1.00)	0.88 (0.76, 1.00)	
Mean ± standard deviation	0.85 ± 0.21	0.85 ± 0.20	
Year 1			
No. of patients	3103	3235	0.56
Median (interquartile range)	0.88 (0.73, 1.00)	0.88 (0.76, 1.00)	
Mean ± standard deviation	0.84 ± 0.22	0.85 ± 0.21	
Year 2			
No. of patients	2872	3044	0.88
Median (interquartile range)	1.00 (0.74, 1.00)	1.00 (0.74, 1.00)	
Mean ± standard deviation	0.85 ± 0.22	0.85 ± 0.21	

Appendix Table A5

EuroQoL Scores of Overall HAT Patient Population versus Quality of Life Subset

	Overall HAT	Non-QoL HAT	QoL HAT	P-value comparing Non-QOL to QOL groups
EuroQoL Visual Analog Scale				
0–100 scale; 0=worst imaginable health, 100=perfect health				
Baseline				
No. of patients	6981	5978	1003	0.61
Median (interquartile range)	80.0 (70.0, 90.0)	80.0 (70.0, 90.0)	80.0 (70.0, 90.0)	
Mean ± standard deviation	75.9 ± 16.2	76.0 ± 16.2	75.5 ± 16.3	
Year 1				
No. of patients	6319	5405	914	0.79
Median (interquartile range)	80.0 (70.0, 90.0)	80.0 (70.0, 90.0)	80.0 (70.0, 90.0)	
Mean ± standard deviation	78.3 ± 15.9	78.4 ± 15.8	77.8 ± 16.6	
Year 2				
No. of patients	5851	5010	841	0.27
Median (interquartile range)	80.0 (70.0, 90.0)	80.0 (70.0, 90.0)	80.0 (70.0, 90.0)	
Mean ± standard deviation	78.0 ± 16.2	78.1 ± 16.3	77.5 ± 16.1	
EuroQoL Single Summary Index (Health State)				
Baseline				
No. of patients	6969	5966	1003	0.65
Median (interquartile range)	0.88 (0.74, 1.00)	0.88 (0.75, 1.00)	0.88 (0.73, 1.00)	
Mean ± standard deviation	0.85 ± 0.20	0.85 ± 0.20	0.85 ± 0.21	
Year 1				
No. of patients	6338	5422	916	0.42
Median (interquartile range)	0.88 (0.74, 1.00)	0.88 (0.74, 1.00)	0.88 (0.73, 1.00)	
Mean ± standard deviation	0.85 ± 0.21	0.85 ± 0.21	0.84 ± 0.22	
Year 2				
No. of patients	5916	5060	856	0.23
Median (interquartile range)	1.00 (0.74, 1.00)	1.00 (0.74, 1.00)	0.88 (0.73, 1.00)	
Mean ± standard deviation	0.85 ± 0.21	0.85 ± 0.21	0.84 ± 0.23	