



## DELIVERABLE 3.3

**Report on impact and economic  
sustainability**

*Emp-H*

*“Empowering Hospital”*

*GA n. 664258*



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<b>Short description of the Deliverable</b>
This document presents the results of the Emp-H study in terms of effectiveness, sustainability and transferability of the proposed intervention. Issues regarding the methods adopted to analyse the Emp-H model are presented as well as the implications useful for the its dissemination in the European health care facilities.

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## Executive summary

**INTRODUCTION** - In the last decade several systematic reviews demonstrated how hospital-based interventions for modifying risky were effective in improving behavioural outcomes. The interventions implemented in the framework of Emp-H project were addressed to patients with chronic diseases, their relatives and hospital workers. Literature supports using 'Teachable Moments' (TM), such as clinical visits, to motivate individuals to spontaneously adopt healthy behaviours. Emp-H is a multi-component intervention including:

- hospital environmental changes,
- recruitment strategy,
- professional-led counseling sessions,
- the maintenance of a network between hospital departments and community institutions that can contribute to sustain the behavioural change.

The counseling session was realized directly in the Hospital Departments during the first contacts with the persons or postponed with an appointment in the Health Promotion Centre (HPC).

**METHODS** - In order to evaluate the capacity of the two organizations to set up a network of salutogenic resources, a report describing health promotion activities activated during the project was analysed. The effect of Emp-H intervention was analysed with a two-arms Randomized Controlled Trial with a 6 months follow up. At the end of the trial the two hospitals principal investigators were surveyed about the resources spent to realize the intervention in order to inform about its sustainability. Lastly, a questionnaire was delivered to the professionals involved in Emp-H project in order to collect information about their level of satisfaction, acceptability of the intervention, reasons for possible early withdrawal, perceived opportunities and barriers to increase the adherence to the proposed intervention.

**RESULTS** - The two hospitals were able to increase the resources aimed at sustaining healthy behaviors during the project period: from 12 to 27 services, and from 3 to 9 actions/policies. A total of 977 subjects were recruited in the Emp-H study, 65.1% of those estimated in the study protocol, and 731 were contacted at follow up. At the follow up survey, both the intervention and the control groups resulted to improve their risk behaviors. The major improvements were observed for sugary drink intake, excessive alcohol consumption and binge drinking. Compared with the control group, in the intervention group it was observed a greater improvement in alcohol protective behaviors and in physical activity. In particular, the best performance was obtained for physical activity. The cost of two years Emp-H project ranged from 34.062€ to 77.701€, while the cost for single counselling session has been estimated to be between 23.6€ and 32€. From the health professionals' perspective, the main barriers for the participants to follow



the recommendations provided during the counselling session were lack of time to attend the proposed resources, and lack of strategies to face risk behaviour relapses.

**CONCLUSIONS** - Emp-H was demonstrated to be a sustainable model able to improve healthy habits among patients, their relatives and health professionals, that could coexist with the actual organization of the European hospitals. Further research could add insights to apply the Emp-H model in other EU countries different from Italy and Spain, and to identify more effective components to improve the model and make it more efficient.



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## **1. The evidence about interventions to promote healthy behavior in the hospital setting**

In the last decade several systematic reviews aimed at studying the effect of hospital-based interventions for modifying risky behaviour were realized. One of the first output of Emp-H was an overview of systematic reviews on the effectiveness of individual and environmental interventions to be realized in the hospitals for empowering patients with non-communicable chronic diseases, their relatives and hospital staff. The searched interventions had to start in the hospital but could continue after hospital discharge. The intervention could be delivered by physicians, nursing staff, psychologists, counsellors or other hospital health professionals, and could include advice, more intensive behavioural therapy, with or without continued contact after hospital discharge. The control intervention could be any less intensive intervention, such as brief advice to quit, or it could be usual care.

Comparing to other unhealthy habits, several systematic reviews were aimed at studying the effect of smoking cessation interventions. High intensity behavioural interventions that begin during a hospital stay and include at least one month of supportive contact after discharge were found to be effective in promoting smoking cessation among hospitalized patients. The effect of these interventions was independent of the patient's admitting diagnosis and was found in rehabilitation settings as well as acute care hospitals (Rigotti 2012). Even a simple advice from a physician has proved to have a small, but not insignificant, effect on cessation rates. Assuming unassisted quit rates of 2 to 3%, a brief advice intervention could increase quitting by a further 1 to 3% (Stead 2013).

Many reviews were interested in studying interventions aimed at reducing heavy alcohol consumption. There are benefits in delivering brief interventions to heavy alcohol users admitted to general hospital wards in terms of reduction in alcohol consumption. However, these findings are based on studies involving mainly male participants (McQueen 2011). Less explored is the effect of interventions focused on lighter consumers, which a further reduction could be beneficial (eg. chronic patients).

Other studies were interested in proving the effectiveness of hospital-based intervention aimed at reducing dietary fat and increasing fruits and vegetables consumption as well as physical activity. An overview of systematic reviews, submitted by the Emp-H's DCU unit in a peer review journal, has proven that hospital-based dietary intervention effectiveness may be increased by frequent contacts with a health professional, providing both diet and physical activity education together, and applying specific behaviour change techniques.

Apart from the evidence about health promotion intervention provided by health care facilities, it should be cited that hospitals are natural settings for preventing disease relapse and promoting healthy behaviour among patients (Demark-Wahnefried 2005; McBride, 2003). In addition to the obvious benefits for patients, a growing body of studies argues that also patients' families and health professionals might benefit from health promotion activities conducted at a hospital setting (Humpel, 2007; Patterson 2010; Osborne 2017; Haug 2018).



The rationale for implementing health promotion activities in the hospital setting is supported by at least three factors. The increased life expectancy and prevalence of people older than 65 in Europe is likely to result in increased prevalence of preventable chronic diseases, such as diabetes and cardiovascular disorders. The hospital is the setting in which these diseases are taken over. Second, health promotion activities in the hospital setting configures as an ideal system to bridge the gap between primary care services and general hospitals. Third, a considerable and diverse body of evidence supports the effectiveness of health promotion programs delivered in health care setting in achieving durable behaviour change which results in decreased risk for chronic medical conditions.

## **2. The Empowering hospital model**

The interventions implemented in the framework of Emp-H project were addressed to patients at risk for diabetes or cardiovascular diseases (e.g., smokers, overweight subjects, or those with hypertension), newly diagnosed patients with a chronic disease (e.g., cardiovascular disease, cancer disease) or patients presenting acute manifestations of an underlying chronic condition (e.g., acute renal failure or acute respiratory distress). Literature supports using 'Teachable Moments' (TM), such as a new diagnosis or an acute manifestation of an underlying chronic condition, to motivate individuals to spontaneously adopt risk-reducing health behaviours (McBride2003).

Targeting such patients allows:

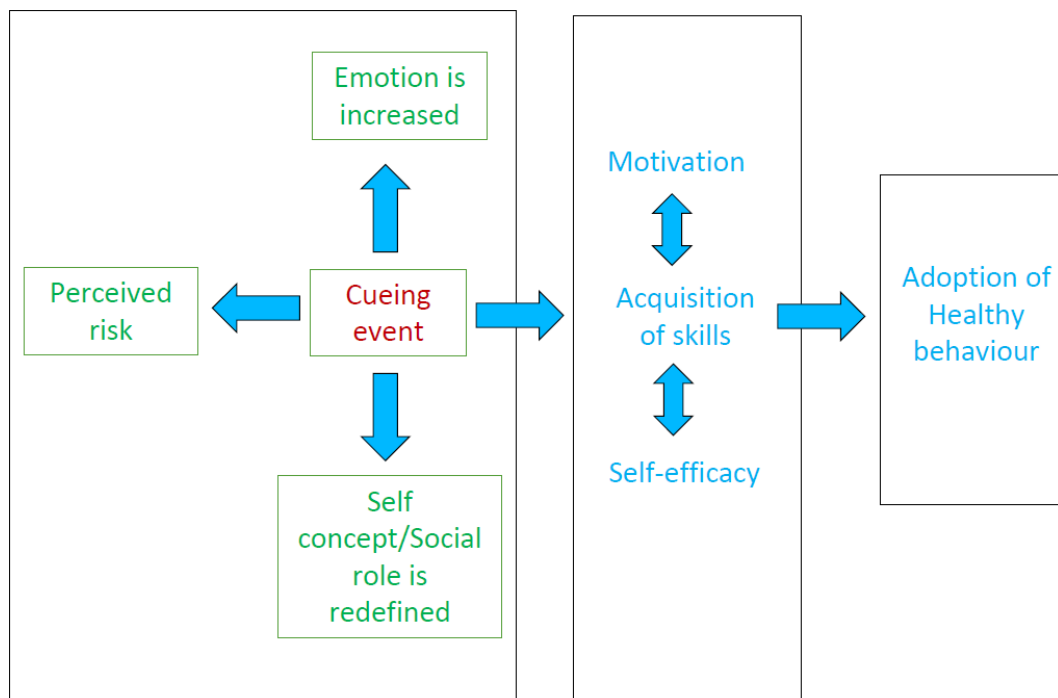
- preventing medical conditions such as diabetes or cardiovascular diseases which are a considerable health concern and economic burden in Member States of the European Union. Patients who present common risk factors (e.g., obesity, hypertension, tobacco smoking) for diabetes or cardiovascular disorders may develop medical conditions which pose their overall health at risk and would be avoidable by implementing appropriate behavioural changes.
- linking and integrating prevention and clinical interventions. Such aspects of care are often separated, although basic research shows that biological, behavioural, and environmental mechanisms are tightly intertwined in the pathogenesis of chronic diseases (Faggiano 2014).

In addition, patients' relatives could also benefit from the interventions both indirectly (by witnessing behavioural change in their relatives) and directly as they are advised undertaking personalised health empowerment pathways and participating to health promotion workshops and group activities. Health professionals are also likely to indirectly benefit from the intervention by accepting the challenge to promote behavioural change, and of course on a voluntary basis as target participants to both individual and group interventions.

Finally, hospital staff, reconsidering their habits, could constitute a role model for patients and their families, and could be more motivated to promote healthy behaviours among them. The periodic health check visits could constitute an ideal moment in which hospital personnel could discuss about patients' habits.

The theoretical basis of the Emp-H intervention is that in hospital setting patients, their relatives and hospital staff encounter different cueing events that activate emotional and cognitive responses able to increase the motivation to improve healthy habits. These cueing events are called “teachable moments” (McBride 2003) (figure 1).

Figure 1. Effect of cueing events on emotional and cognitive processes and on behavior (Adapted from McBride 2003).



The intervention proposed by the Emp-H project was realized directly in the Hospital Departments during the first contacts with the persons or postponed with an appointment in the Health Promotion Centre (HPC).

The HPC, a new structure ideally belonging to the Health Direction, was experimented in Biella Hospital and it was appointed to at least five activities in the framework of this project:

- (1) planning and administration of environmental changes applied within the hospital (e.g., implementation of an antismoking policy, supply of healthy food at the hospital canteen & cafeteria and hospital advertising for health promotion);
- (2) organisation and communication of counselling services and workshops to experience healthy behaviours (e.g., healthy eating, physical activity);
- (3) administration of proper training for health professionals involved in counselling activities;
- (4) measurement of health objectives assessed in this project;
- (5) coordination of health promotion initiatives planned jointly with public and private facilities in the community (e.g., discounts for gyms and sport facilities, outdoor walking and trekking, healthy leisure and tourism, pet combined or assisted activities, leisure-time and socially innovative



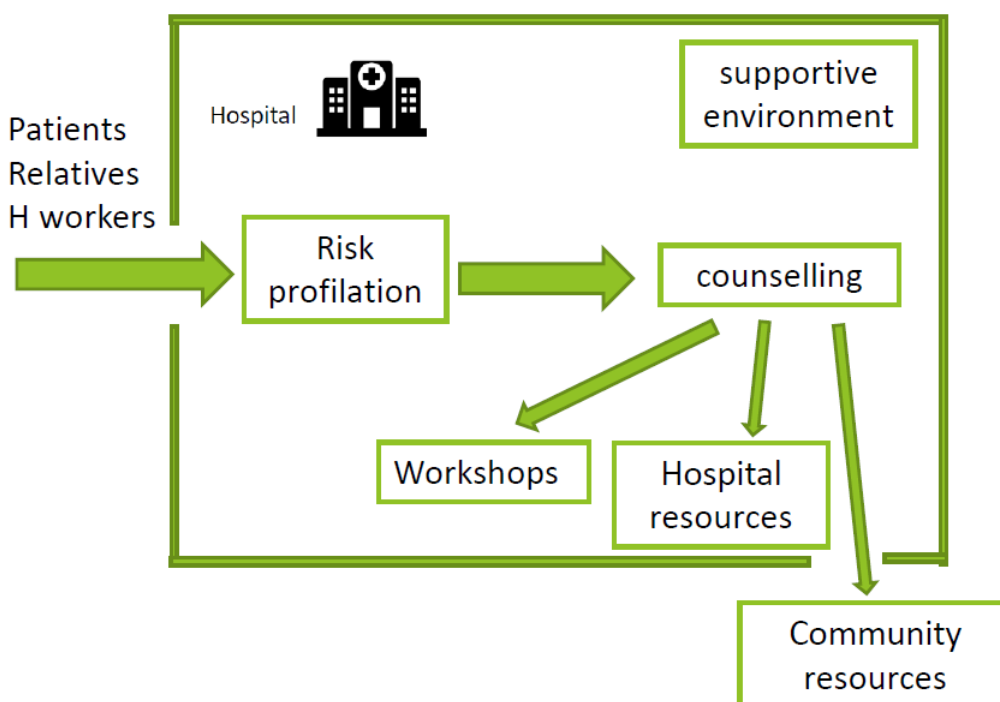


events, open air festival and games), and with workplaces in the community (e.g., for the promotion of healthy workplaces).

Activities developed within the hospital were aimed to target especially patients, but within Emp-H model they were open also to patients' families and the hospital staff. Figure 2 presents an overview of the Emp-H model in which subjects in contact with the hospital received:

- **environmental support** for behavioural change (smoking policies, alcohol policies, social marketing campaigns);
- **risk profilation activity** and provision of information to change unhealthy behaviours offered during periodic visits, considered 'teachable moments', in which patients, relatives and hospital staff would have the greater emotional and cognitive readiness to behaviour change;
- for those subjects recruited in the intervention group of Emp-H study, an **intensive counselling session** delivered by psychologists or nurses aimed at increasing motivational readiness to change unhealthy behavior;
- **interactive workshops** on health-related issues (such as healthy cooking and home exercise programs) and **health promoting initiatives** (e.g., self-help groups, smoking cessation centre, community gyms, etc.) realized in the hospital as well as in the hospital catchment area, readily available also outside of the teachable moments.

Figure 2. Overview of the Empowering Hospital model.





### **3. Emp-H Implementation Trial: a real-world experiment to validate a hospital organizational model aimed at promoting healthy behaviors**

The first hypothesis of the Emp-H study was that a coordinated approach to implement supportive resources aimed at sustaining healthy habits would enforce a network of salutogenic resources within the hospital and in the hospital catchment area.

The second hypothesis under study was that the introduction of personalized interventions in hospital clinical pathways could be effective in significantly improving healthy behaviours in different target populations. Risk factors under study were: smoking, alcohol consumption, sedentary behavior and unhealthy diet.

At the end of the Emp-H study, intervention costs were estimate in order to inform policy makers and hospital managers about the sustainability of the Emp-H model.

Lastly, health professionals involved in Emp-H were surveyed to catch their vision about the project in order to discuss its implementation and transferability.

The study was realized under real-world conditions. This means that the project was developed step by step starting from the constitution of a project group collecting different stakeholders of the hospital organization to implement the model within the hospital organization, to the results presentation to the hospitals' health professionals.

#### **3.1 Method adopted to measure the effect of Emp-H on the organizational outcome**

In order to evaluate the capacity of the two organizations (Ospedale degli Infermi, Biella, Italy and Hospital Universitario y Politécnico La Fe en Valencia, Spain) to set up a network of salutogenic resources (health promotion activities that were offered to the study participants by the healthcare organizations as well as by the community organizations), it was asked to the two project coordinators to fill in a report describing health promotion activities to sustain healthy lifestyle presented to the study participants. The activities could be realized in the hospital by departments and services, as well as in the hospital catchment area by public and private organizations. For this purpose, two surveys were realized, one preceding the experimentation (at month 9-January 2016) and one at the end of the intervention (at month 30-October 2017). The questionnaire adopted for this purpose is described in the deliverable D3.1. A simple comparison between the resources before and after the study was presented.

#### **3.2 Method adopted to measure the effect of Emp-H on the individual outcomes**

##### **3.2.1 Design and interventions**

The Emp-H study protocol was presented in the deliverable 3.1 and below described. The effect of Emp-H on participants' behavior was studied through a two-arms effectiveness trial in which participants were randomized to an intervention based on a single counselling session and the



facilitating access to health promoting resources (group 1), and to an intervention consisting on a single basic advice (group 2). Both participants in group 1 and in group 2 benefited from environmental interventions (health policies and social marketing campaigns), a risk profilation session aimed at detecting behavioural risk factors and a brief advice-based intervention delivered by health professionals. Subjects allocated in the intervention group as well as in the control group were surveyed by telephone after 6 months from the counselling/basic advice intervention.

### The counseling session

The counseling session was conducted by psychologists in Italy and by nurses in Spain. The intervention lasted about 30 minutes and was realized just after the risk profilation in Spain and on appointment in Italy. The main goal of the counselling was to identify barriers and opportunities to modify risky behaviours, taking the chance of the teachable moment of the visits. A further difference between the two sites consisted in the location where the counseling was provided: in the same department where subjects were profiled in Spain and in a specific ambulatory in the hospital, the HPC, in Biella.

The supportive resources offered during the counselling session were free of charge and consisted in interactive workshops, services (such as smoking cessation centers, walking groups, etc.), and opportunities (walking paths, healthy menu in the hospital canteen, etc.).

### 3.2.2 Participants

Participants belong to three different populations: 1) outpatients suffering from a chronic disease, 2) outpatients caregivers, and 3) hospital workers. Subjects were enrolled during specific activities performed in the hospital setting assumed to be appropriate teachable moment for reconsidering their habits. Eligible subjects had an age between 40 and 75.

In Biella eligible outpatients were those with: 1) new diagnosis of type II diabetes (ICD-9-CM: 250), 2) new diagnosis of overweight (ICD-9-CM 278.02) and with BMI >27, 3) recent diagnosis of stroke (ICD-9-CM: 410) in follow up in the last year, 3) recent diagnosis of breast cancer (ICD-9-CM: 174), prostate cancer (ICD-9-CM: 185), and colon cancer (ICD-9-CM: 153-154) in follow up in the last year. Outpatients were enrolled during a medical examination. In Valencia eligible patients were inpatients in Cardiology and Pulmonary departments referred to be evaluated for inclusion in *Hospital at Home program*, a specific service aimed at providing healthcare and treatment to the patients at their homes (Mendoza 2009) preserving hospital conditions.

In Biella outpatients' caregivers and family members were recruited when accompanying patients to the medical examination, while in Valencia they were recruited in Primary Care Centers belonging administratively to the Hospital Universitario y Politécnico La Fe when they accompany their relatives.



Hospital workers were recruited during the compulsory periodic health check visits at the Department of Occupational Risk in Biella and voluntary based at the Occupational Risk Prevention Area in Valencia.

In general, subjects were considered not eligible if they demonstrated insufficient competence and language skills to understand the study's objectives and procedures, as stated by the personnel appointed to recruit the subjects, and for patients if they present a life expectancy shorter than 2 years as stated by the doctor currently treating them.

### **3.2.3 Recruitment procedures**

Subjects were screened and profiled with a specific questionnaire aimed at identifying risky behavior (see D3.1, annex 2). In Biella eligible patients and their relatives/caregivers were contacted by trained volunteers or hospital nurses, while in Valencia only by hospital nurses. Hospital workers both in Biella and Valencia were contacted during the periodical health check by a hospital nurse. The recruiters were responsible to 1) check eligibility criteria, 2) introduce the study, 3) obtain informed consent, and 4) complete the questionnaire. Afterwards, patients and relatives who have consented to participate received a structured brief advice on healthy behaviors. In Valencia nurses were able to know the subject assignment after the questionnaire completion opening a specific envelope containing allocation information. In Biella it was the psychologist responsible for the counselling who contacted the subjects that were assigned to the intervention group few days after the brief advice session. A flowchart of the study recruitment procedure is given in Figure 3.

### **3.2.4 Randomization, blinding and other study procedures**

The questionnaire, provided by a code useful for the following allocation procedure, was administered during the programmed visits by volunteers and health professionals blinded to allocation arm. Only during the counselling session participants were aware of the allocation as the specialist could identify the allocation of the participant through a list in which every code was assigned to a condition. No incentives were offered to participants for their time in completing the assessments. Data entry was managed electronically by the counselling specialists both in Biella and in Valencia.

### **3.2.5 Sample size**

Sample size calculations were carried out conservatively on the basis of the risk behaviour with the lowest prevalence in the adult population targeted by this project, i.e. smoking, which is approximately 25% in the country with the lowest prevalence between those involved in the project (WHO 2015). We assumed 23% smoking prevalence among participants receiving the



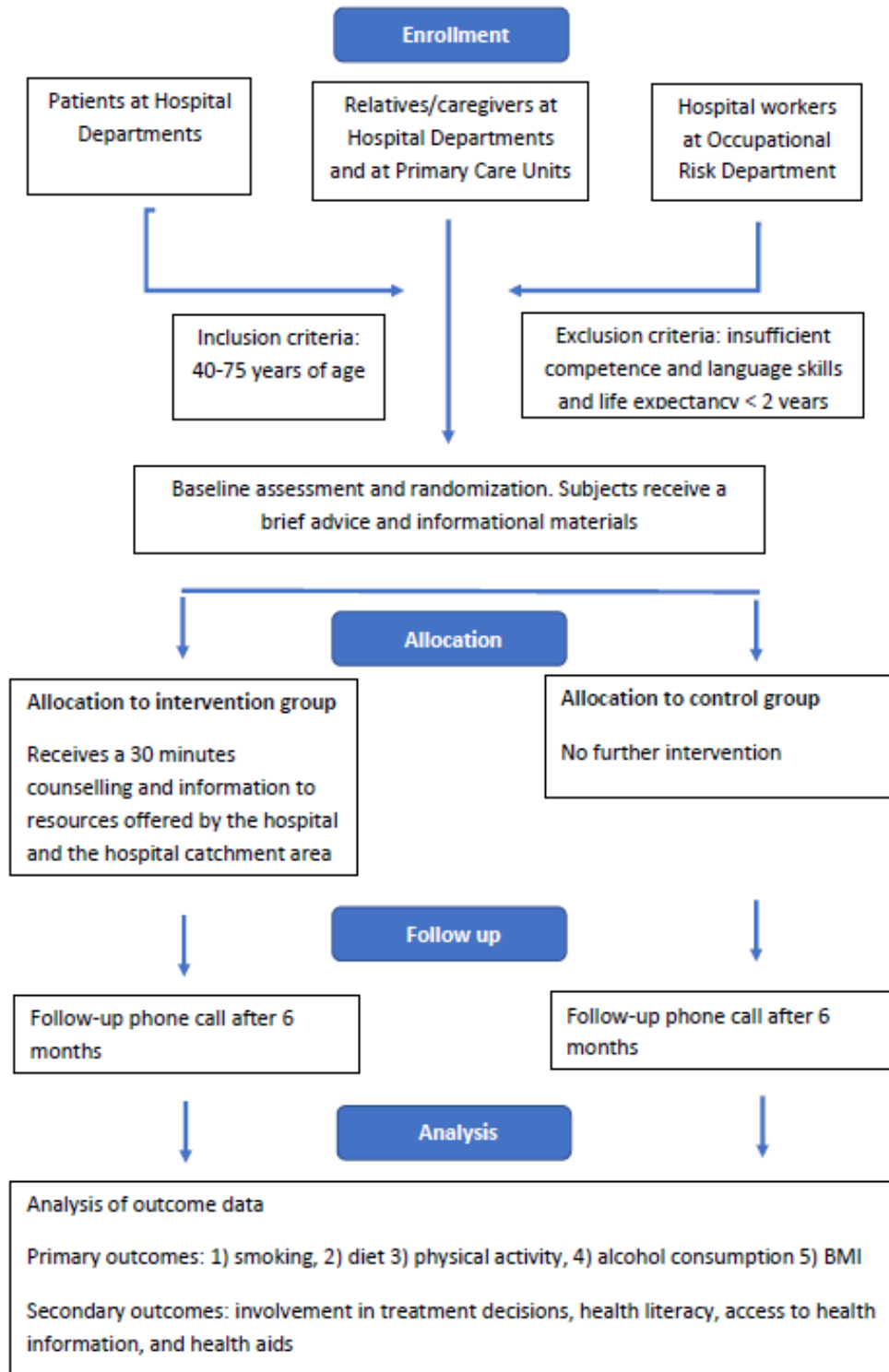
control condition ( $\pi_1$ ), i.e. health professional advice for smoking cessation. We anticipated an intervention effect (risk ratio) of 0.6, which results in 13,8% smoking prevalence among participants in the intervention group ( $\pi_2$ ) who will undertake a comprehensive smoking cessation intervention in addition to physician advice. Sample size calculations were carried out assuming 5% type 1 error ( $\alpha$ ), indicating the probability of incorrectly rejecting the null hypothesis of no difference in smoking prevalence between study groups, and 80% power ( $\beta$ ), which is the probability of correctly rejecting the null. The formula used to estimate the overall sample size given the above-mentioned assumptions can be summarised as follows:

$$\text{Sample size} = 2 \times f(\alpha, \beta) \times [\pi_1 \times (100 - \pi_1) + \pi_2 \times (100 - \pi_2)] / (\pi_1 - \pi_2)^2$$

in which  $f(\alpha, \beta)$  is function of the assumed levels of type 1 and type 2 errors and is equal to 7.85 when  $\alpha$  is 5% and  $\beta$  is 80%. With this procedure, we estimated an overall sample size of approximately 500 patients, 500 relatives, and 500 hospital workers.



Figure 3. Consolidated Standards of Reporting Trials (CONSORT) flow chart. CONSORT flow chart illustrating all steps in the study from enrolment to allocation and follows up. Inclusion and exclusion criteria are also specified as well as outcome measures.





### 3.2.6 Outcome evaluation

Primary endpoints under study were: 1) smoking behaviour (smoking status, number of cigarettes smoked, time to first cigarette smoked after waking up), 2) diet (frequency of fruit and vegetables and sweet drink consumption), 3) physical activity (frequency and duration of moderate-intensity and vigorous-intensity physical activity), 4) alcohol consumption (frequency and amount of alcohol units consumption, frequency of binge drinking), 5) BMI calculated as weight in kilograms divided by height in meters squared.

Secondary endpoints under study were empowerment measures declined as level of subjects' involvement in treatment decisions, health literacy, access to health information, access to decision-making aids. For this goal, it was adopted the Questionnaire for Patient Empowerment Measurement (Ünver 2013).

Table 1 presents an overview of the variables under study, their categorization and recoding.

Table 1 Overview of the main variables under study

Variable	Categories	Recode
Gender	Male Female	
Age	40-60 60-75	
Educational attainment	No-primary secondary degree	low education middle education high education
BMI	<18.50 18.5-25.0 25.0-30 sovrappeso >30 obesità	underweight normal weight overweight Obese
<b>Behaviour</b>		
Smoking	No Yes	smoker
Fruit and vegetable consumption	>5 portions/day <=4 portion/day	optimal insufficient
Sugary drink consumption	>1 glass/day <= 1 glass/day	Risky not risky
Alcohol consumer	Never >2 units/month	not alcohol consumer alcohol consumer
Alcohol amount (among consumers)	<=1 unit women/<=2 units men >1 unit women /> 2 units men	correct amount excessive amount
Binge drinking (among consumers)	>1 month 4 units women/5 units men) in one occasion	binge drinker
Physical activity	<150 minutes moderate or <75 minutes vigorous PA >150 minutes moderate or >75 minutes vigorous PA	inactive Active



### **Empowerment measures**

Self-efficacy	0-10
Information about hospital opportunities	0-10
Propensity to follow health professional advice	0-10
Search for additional information	0-10
Having a supportive environment	0-10
Drawing health professional attention	0-10

### **3.2.7 Analyses**

Descriptive statistical analyzes were conducted using the information collected at the baseline. For categorical variables, N and % were reported, while for continuous variables the mean and standard deviation values were reported.

The evaluation of a correct randomization was carried out by comparing the intervention group and the control group to the baseline using the chi-square test. The tables are not reported in the results as there were no significant differences.

In order to evaluate the presence of baseline differences between patients, relatives and hospital staff, approximate (Chi square) or exact (Fisher) association tests were performed and the obtained pvalue values were reported. Subsequently, the analyzes were conducted keeping these groups together to avoid the occurrence of scattered data phenomena and the categories represented below.

As the study aims at assessing the presence of differences between the intervention group and the control group for some health outcomes (fruit and vegetables and sugar consumption, smoking, alcohol abuse, binge drinking, physical activity), it was decided to implement different univariate analyzes for each factor analyzed. The analyzes were restricted to the subjects that presented the risk factor at the baseline. For each outcome, 2 \* 2 contingency tables were constructed and the Relative Risk (RR) was calculated with the respective 95% confidence interval. The event of interest is represented by the subjects who had removed the risk factor from the second questionnaire (post).

Since we had a lot of missing data at post survey, we proceeded by attributing the data through the creation of a "best" and "worst" scenario. In the first case all the missing values were considered as potential successes, i.e. as if they had removed the risk factor, while in the second case all the missing ones were evaluated as subjects that did not improve over time. The inclusion of missing values was conducted considering separately treated and not treated. The respective RRs and CIs at 95% were then calculated.





### 3.3 Emp-H costs

At the end of the trial the two hospitals principal investigators were surveyed about the resources spent to realize the intervention in order to inform about its sustainability. The cost of the project was calculated on hourly rate and on the amount of time spent by all the involved professionals to deliver the intervention. The survey was realized in two phases: the first, carried out in month 28-September 2017, was aimed at calculating the cost of the counseling session per person, while the second, realized in month 35-March 2018, was concentrated on the effort to create and to maintain the Emp-H model within the hospital. Costs derived from equipment and other depreciable assets were also considered in the analyses.

### 3.4 Health professionals' point of view of Emp-H

A questionnaire was delivered to the professionals involved in Emp-H project in order to collect information about their level of satisfaction, acceptability of the intervention, reasons for possible early withdrawal, perceived opportunities and barriers to increase the adherence to the proposed intervention. During the drafting of D3.1, it was planned to interview by phone study participants, but for practical reasons it was then decided to use a questionnaire. The survey was carried out at the end of the follow up at month 29-September 2017. The questionnaire was presented in the deliverable D3.1.

## 4. RESULTS

### 4.1 Emp-H effect on the organizational outcomes

The two hospitals were able to increase the offer of resources aimed at sustaining healthy behaviors during the project period. Services oriented to empower patients, relatives and health professionals more than doubled in the second part of the project (table 2), from 12 to 27. The same result was observed in the capacity of the hospital and the community to increase policies and environmental conditions: from 3 to 9 actions realized (table 3). The effect can be mainly attributed to the contribution of Biella Hospital that invested in the implementation of a smoking policy inside and outside the buildings, the provision of healthy food in the hospital canteen and in the promotion of walkable pathways. Comparing the risk factors, the majority of services and policies were focused on diet and physical activity thanks to the contribution of community associations. In addition to the results detected with the survey, a *report agreement between HPC and resources at community level* (Milestone 11) lists and describes the organizations comprised in the networks created within the Emp-H project in each site.



Table 2. Emp-H effect on capacity building (supportive services inside the hospital and in the hospital catchment area).

	From May 2015 to June 2016				From July 2016 to October 2017			
	smoking	alcohol	diet	PA	smoking	alcohol	diet	PA
<b>ASL BI</b>	1) 4 SCCs outside the hospital 2) GPs training	1) ACC outside the hospital 2) self-help groups offered by AA 3) workshops	1) counselling delivered by a hospital dietitian and by a community association	1) walking groups 2) community exercise therapy gym 3) marked walking routes 4) facilitated access to a partner gym	1) 1 hospital SCC 2) SHM	1) hospital self-help group 2) SHM	1) nutrition counselling by a community association 2) recipes e-book 3) diet course 4) nutrition website 4) SHM	1) Nordic walking courses 2) metabolic fitness courses 3) "Health when you walk" project 4) Walking school 5) "I walk" initiative
<b>LA FE</b>	1) intensive counselling and delivery of SHM	1) Access to a PCC specialized in alcohol reduction	1) intensive counselling and delivery of SHM material	1) intensive counselling and delivery of SHM material	1) supportive website	1) supportive website	1) supportive website	1) supportive website

PA: physical activity; SCC: smoking cessation center; ACC: alcohol cessation center; AA: Alcoholics Anonymous; PCC: primary care center; SHM: self-help material



Table 3. Emp-H effect on capacity building (healthy policies inside the hospital and in the hospital catchment area)

	From May 2015 to June 2016				From July 2016 to October 2017			
	smoking	alcohol	diet	PA	smoking	alcohol	diet	PA
<b>ASL BI</b>	1) smoking ban billboards  2) smoking ban training for hospital workers		1) healthy food messages and healthy menu in the hospital canteen		1) smoking ban extended to hospital entrances		1) healthy canteen open to the public  2) healthy food corner in the canteen  3) canteen' take-away service	1) community walking paths around the hospital  2) 25/27 villages around the hospital adhere to the Toronto Charter

## 4.2 Emp-H effect on the individual outcomes

### 4.2.1 Recruitment process and deviations from the study protocol

A total of 977 subjects were recruited, 65.1% of those estimated in the study protocol (table 4). Comparing to the estimated number of subjects to be recruited, patients and workers were about 2/3, while relatives were 1/2. The difference between the number of the recruited subjects (996), as described in the deliverable 1.3, and those considered for the analysis is due to a protocol deviation in the enrollment procedures concerning the eligibility criteria: 19 subjects were less than 40 and more than 75 years old, hence they were excluded from the analyses.

Since the sample has not been completed, it is possible to note a disproportion in the two groups (more in the intervention than in the control group). The disproportion was then reversed at follow up as 111 subjects allocated in the intervention group didn't attend the appointment at HPC and they were no more contacted for the follow up by ASLBI site. This additional protocol deviation produced in general a loss of 24,8% of the recruited sample.



Table 4. Overview of the subjects recruited in the Emp-H study (absolute number and percentage).

BASELINE

	Estimated N	Recruited n (%)
Patients	500	363 (72.6)
Relatives	500	270 (54.0)
Workers	500	344 (68.8)
Total	1500	977 (65.1)

Differences between Intervention and Control groups at baseline

	Recruited N	Control n (%)	Intervention n (%)
Patients	363	174 (47.9)	189 (52.1)
Relatives	270	118 (43.7)	152 (56.3)
Workers	344	170 (49.4)	174 (50.6)
Total	<b>977</b>	462 (47.3)	515 (52.7)

FOLLOW UP

	Recruited N	Followed N (% recruited)
Patients	363	248 (68.3)
Relatives	270	195 (72.2)
Workers	344	288 (83.7)
Total	977	731 (74.8)

Differences between Intervention and Control groups at follow up

	Followed	Control	Intervention
Patients	248	141 (56.9)	107 (43.1)
Relatives	197	100 (51.3)	95 (48.7)
Workers	289	154 (53.5)	134 (46.5)
Total	<b>731</b>	395 (54.0)	336 (46.0)

**4.2.2 Characteristics of the sample (patients, relatives and hospital workers) at baseline**

The sample was mainly composed by female subjects as the majority of hospital workers and patients' relatives were women (table 5). People between 40 and 60 years old were the majority for the effect of the workers sample, while among patients, 70% was constituted by people aged over 60 years. Concerning the educational attainment, low education levels were present in 49% of the recruited subjects, and in particular in the majority of the patients and relatives sample, while middle education was more represented among workers. Concerning the BMI, 53.8% of the whole sample was overweight or obese. From our observation, patients and relatives had a higher BMI than hospital workers. About diet outcomes, the recommended consumption of 5 a day portions of fruits and vegetables was followed only by 15% of the sample, while 15.9% used to consume only one portion or less. Risky consumption of sugary drink was present in 5.3% of the



sample. Smoking habit involved 23% of the subjects. 68.8% of the sample was alcohol consumers, while risky alcohol intake affected 14.4% of the consumers, and, in particular, 22.4% of patients group. Problematic alcohol consumption, represented by binge drinking, involved 14.7% of the alcohol consumers, especially among patients. Almost half of the sample followed recommended amount of physical activity, more among patients and relatives than among hospital workers. Concerning empowerment measures, patients were more inclined than other groups to follow health professional advices and perceived their environment as supportive to practice healthy behaviours.

Table 5. Characteristics of the whole sample and among target groups at baseline: socio-demographic, behaviours and empowerment. For categorical variable number (N) and percentage (%), while for numeric variables mean and standard deviation are reported. Relative frequencies for missing data are also reported.

Variable	Level	All n (%)	Patients n (%)	Relatives n (%)	Workers n (%)	p value
Gender	male	<b>338(34.6)</b>	207(57.0)	77(28.5)	54(15.7)	<0.0001
	female	<b>639(65.4)</b>	156(43.0)	193(71.5)	290(84.3)	
Age	40-60	<b>552(56.5)</b>	107(29.5)	134(49.6)	311(90.4)	<0.0001
	60-75	<b>425(43.5)</b>	256(70.5)	136(50.4)	33(9.6)	
Educational attainment	<i>Missing</i>	<b>19(1.9)</b>		3(1.1)	5(1.5)	<0.0001
	Low	<b>479(49.0)</b>	244(69.3)	181(67.0)	54(15.7)	
	Middle	<b>363(37.2)</b>	92(26.1)	77(28.5)	194(56.4)	
	High	<b>116(11.9)</b>	16(4.5)	9(3.3)	91(26.5)	
Nationality	<i>Missing</i>	<b>176(18.0)</b>		102(37.8)	19(5.5)	0.3661
	Italian or Spanish	<b>787(80.6)</b>	303(98.4)	163(60.4)	321(93.3)	
	Other	<b>14(1.4)</b>	5(1.6)	5(1.9)	4(1.2)	
Weight		<b>71.3±15.5</b>	77.6±17.7	71.5±14.6	67.6±13.8	<0.0001
Height		<b>165.2±8.5</b>	166.5±8.8	164±8.4	164.7±7.9	0.0044
BMI	<i>Missing</i>	<b>5(0.5)</b>		1(0.4)		<0.0001
	Underweight	<b>28(2.9)</b>	10(2.8)	9(3.3)	9(2.6)	
	Normal weight	<b>418(42.8)</b>	111(30.9)	103(38.1)	204(59.3)	
	Overweight	<b>299(30.6)</b>	122(34.0)	103(38.1)	74(21.5)	
	Obese	<b>227(23.2)</b>	116(32.3)	54(20.0)	57(16.6)	
Is body weight detrimental to your health status?	<i>Missing</i>	<b>7(0.7)</b>		2(0.7)	3(0.9)	0.0115
	No	<b>547(56.0)</b>	182(50.4)	156(57.8)	209(60.8)	
	Yes	<b>423(43.3)</b>	179(49.6)	112(41.5)	132(38.4)	
Fruit and vegetable consumption	<i>Missing</i>	<b>4(0.4)</b>		2(0.7)	1(0.3)	0.3766



	Ottimal	<b>147(15.0)</b>	61(16.9)	45(16.7)	41(11.9)	
	Insufficient	<b>826(85)</b>	301(83.1)	223(82.6)	302(87.8)	
Sugary drink consumption	<i>Missing</i>	<b>7(0.7)</b>		1(0.4)	3(0.9)	0.0139
	Not risky	<b>918(94.0)</b>	338(93.9)	248(91.9)	332(96.5)	
	Risky	<b>52(5.3)</b>	22(6.1)	21(7.8)	9(2.6)	
Correct diet	<i>Missing</i>	<b>23(2.4)</b>		9(3.3)	6(1.7)	0.6191
	No	<b>302(30.9)</b>	119(33.5)	81(30.0)	102(29.7)	
	Yes	<b>652(66.7)</b>	236(66.5)	180(66.7)	236(68.6)	
Smoking	<i>Missing</i>	<b>7(0.7)</b>		2(0.7)	2(0.6)	0.1436
	No	<b>745(76.3)</b>	289(80.3)	200(74.1)	256(74.4)	
	Yes	<b>225(23.0)</b>	71(19.7)	68(25.2)	86(25.0)	
Alcohol consumption	<i>Missing</i>	<b>16(1.6)</b>		4(1.5)	4(1.2)	0.0009
	Not consumer	<b>289(29.6)</b>	118(33.2)	94(34.8)	77(22.4)	
	Consumer	<b>672(68.8)</b>	237(66.8)	172(63.7)	263(76.5)	
	Correct ammount	<b>575(85.6)</b>	184(77.6)	150(87.2)	241(91.6)	<0.0001
	Excessive ammount	<b>97(14.4)</b>	53(22.4)	22(12.8)	22(8.4)	
	Binge drinking No	<b>573(85.3)</b>	195(82.3)	145(84.3)	233(88.6)	0.1269
	Binge drinking Yes	<b>99(14.7)</b>	42(17.7)	27(15.7)	30(11.4)	
Vigourous physical activity	Not specified	<b>740(75.7)</b>	296(81.5)	225(83.3)	219(63.7)	<0.0001
	Yes	<b>237(24.3)</b>	67(18.5)	45(16.7)	125(36.3)	
	Minutes/week	<b>141.7±130.1</b>	149.9±128.7	203.4±183	115.1±97	0.0251
Moderate physical activity	Not specified	<b>222(22.7)</b>	95(26.2)	65(24.1)	62(18.0)	0.0292
	Yes	<b>755(77.3)</b>	268(73.8)	205(75.9)	282(82.0)	
	Minutes/week	<b>132.7±117.8</b>	156.3±126.5	167.1±125.7	85.1±82.8	<0.0001
Active	No	<b>391(50.6)</b>	130(46.9)	93(45.5)	169(55.4)	0.0046
	Yes	<b>382(49.4)</b>	147(53.1)	116(55.5)	128(44.6)	
Self-efficacy		<b>7.8±0.4</b>	7.4±2.7	7.5±2.5	7.2±2.4	0.3125
Information about hospital opportunities		<b>5.5±0.5</b>	5.8±3.5	5.9±3.4	4.9±2.9	0.0007
Propensity to follow health professional advice		<b>6.7±0.4</b>	7.3±2.6	7.1±2.5	6.5±2.4	0.0001
Search for additional information		<b>5.6±0.5</b>	5.6±3.3	5.9±3.1	6.3±2.5	0.0031
Having a supportive environment		<b>6.7±0.4</b>	7.4±2.7	6.9±2.8	6.5±2.4	<0.0001
Drawing health professional attention		<b>5.6±0.5</b>	5.9±3.4	6.1±3.2	5.3±2.8	0.0176



For the analyses concerning the intention to change behaviours, it should be considered the high prevalence of missing data, in particular for diet improvement and for alcohol reduction (table 6). For this reason, a comment on the intention of changing these behaviours could be biased. Conversely, it is possible to highlight that 12.8% of the sample intended to improve in the short term their physical activity levels and that 10.7% of the smokers was interested in quitting within the following month. This last aspect was particularly evident among patients who smoke.

Table 6. Intention to change behavior in the whole sample and among target groups at baseline

		All n (%)	Patients n (%)	Relatives n (%)	Workers n (%)	p value
Weight	<i>Missing</i>	<b>478(48.9)</b>		131(48.5)	184(53.5)	0.2049
	No changes within the next 6 months	<b>62(6.3)</b>	22(11.0)	24(8.9)	16(4.7)	
	Reduction within the next 6 months	<b>207(21.2)</b>	79(39.5)	58(21.5)	70(20.3)	
	Reduction within the next month	<b>92(9.4)</b>	42(21.0)	17(6.3)	33(9.6)	
	Reduction within the last 6 months	<b>138(14.1)</b>	57(28.5)	40(14.8)	41(11.9)	
Diet	<i>Missing</i>	<b>660(67.6)</b>		182(67.4)	233(67.7)	0.0073
	No changes within the next 6 months	<b>59(6.0)</b>	21(17.8)	22(8.1)	16(4.7)	
	Improving within the next 6 months	<b>140(14.3)</b>	47(39.8)	41(15.2)	52(15.1)	
	Improving within the next month	<b>62(6.3)</b>	31(26.3)	17(6.3)	14(4.1)	
	Improving within the last 6 months	<b>56(5.7)</b>	19(16.1)	8(3.0)	29(8.4)	
Alcohol consumption	<i>Missing</i>	<b>352(36.0)</b>		104(38.5)	159(46.2)	0.9775
	No changes within the next 6 months	<b>474(48.5)</b>	205(74.8)	128(47.4)	141(41.0)	
	Reduction within the next 6 months	<b>53(5.4)</b>	24(8.8)	13(4.8)	16(4.7)	
	Reduction within the next month	<b>43(4.4)</b>	21(7.7)	9(3.3)	13(3.8)	
	Reduction within the last 6 months	<b>55(5.6)</b>	24(8.8)	16(5.9)	15(4.4)	
Physical activity	<i>Missing</i>	<b>55(5.6)</b>		12(4.4)	20(5.8)	<0.0001
	No changes within the next 6 months	<b>365(37.4)</b>	162(47.6)	111(41.1)	92(26.7)	
	Improving within the next 6 months	<b>356(36.4)</b>	116(34.1)	95(35.2)	145(42.2)	
	Improving within the next month	<b>125(12.8)</b>	46(13.5)	29(10.7)	50(14.5)	
	Improving within the last 6 months	<b>76(7.8)</b>	16(4.7)	23(8.5)	37(10.8)	
Quit smoking *	<i>Missing</i>	<b>18(8.0)</b>		2(2.9)	10(11.6)	0.0417
	No changes within the next 6 months	<b>104(46.2)</b>	24(36.9)	36(52.9)	44(51.2)	
	Quit within the next 6 months	<b>79(35.1)</b>	28(43.1)	25(36.8)	26(30.2)	
	Quit within the next month	<b>24(10.7)</b>	13(20.0)	5(7.4)	6(7.0)	

\*among smokers



#### 4.2.3 Characteristics of the sample at follow up: the effect of Emp-H intervention.

At the follow up survey, both the intervention and the control groups resulted to improve their risk behaviors (table 7). The major improvements were observed for sugary drink intake, excessive alcohol consumption and binge drinking. Compared with the control group, in the intervention group it was observed a greater improvement in alcohol protective behaviors and in physical activity. In particular, the best performance was obtained for physical activity where people in the intervention group doubled the chance to become sufficiently active after 6 months from the counseling. To confirm this hypothesis, it was performed a sensitivity analysis in order to include also those subjects lost at follow up (table 8). Therefore, it was tested the effect of the intervention in two different scenarios, one in which all subjects lost at follow up improved their habits (best scenario), and one in which they didn't change (worst scenario). In the worst-case scenario, subjects in the intervention group were similar to those in the control group except from physical activity (RR 1.73, 95%CI 1.16-2.59).

Table 7. Improvement differences between intervention and control groups at follow up

	Intervention N (%improvements)	Control N (%improvements)	RR	95% CI
Insufficient consumption of Fruits & vegetables	285 (2.46)	320 (2.81)	0.88	0.33-2.31
Excessive consumption of Sugary drinks	18 (50.00)	22 (45.45)	1.10	0.57-2.11
Smoking	73 (12.33)	84 (9.52)	1.29	0.53-3.18
Alcohol abuse	39 (58.97)	35 (34.29)	<b>1.72</b>	<b>1.01-2.92</b>
Binge drinking	35 (82.86)	142 (61.36)	<b>1.35</b>	<b>1.02-1.78</b>
Physical inactivity	206 (28.64)	245 (14.69)	<b>2.24</b>	<b>1.54-3.25</b>

Table 8. Improvement differences between intervention and control group at follow up: best and worst-case scenario (sensitivity analysis).

Improvements	Missing		Best scenario		Worse scenario	
	Intervention	Control	RR	95% CI	RR	95% CI
Insufficient consumption of Fruits & vegetables	150	71	<b>1.76</b>	<b>1.40-2.22</b>	0.70	0.26-1.86
Excessive consumption of Sugary drinks	8	4	1.21	0.77-1.91	0.90	0.44-1.85
Smoking	52	16	<b>2.03</b>	<b>1.37-3.01</b>	0.90	0.36-2.25
Alcohol abuse	19	4	<b>1.77</b>	<b>1.17-2.66</b>	1.29	0.73-2.27
Binge drinking	13	7	<b>1.31</b>	<b>1.05-1.64</b>	1.14	0.81-1.61
Physical inactivity	92	43	<b>1.93</b>	<b>1.54-2.42</b>	<b>1.73</b>	<b>1.16-2.59</b>





### 4.3 Economic sustainability

In the cost analyses it was calculated the costs concerning the Emp-H model enforcement within the hospitals as well as the cost for each person treated, while we couldn't estimate the effort to realize environmental changes. Table 9 summarizes the costs considered for the analyses based on the hourly rates of the professionals involved in the project and on the price of every single supportive material.

Table 9: Professionals hourly rates and supportive materials costs

Professional role	Hourly rate (€/h)
Project Manager (Spain)	24.94€
Physician (Italy)	43.34€-65.06€
Physician (Spain)	36.62€
Psychologist senior (Italy)	41.87€
Psychologist junior (Italy)	23.89€
Hospital nurse (Italy)	19.04€
Hospital and Primary care nurse (Spain)	23.89€
<b>Supportive materials</b>	
Profiling tool booklet (each)	1.54€
Information leaflet (each)	0.15€

The Emp-H management costs were calculated taking into account the efforts spent to coordinate the project and to train health professionals. It was also considered the time dedicated by the staff involved in the project to attend the periodical project meetings. Two years was the time frame to activate and maintain the project. Table 10 offers an overview of the costs to enforce Emp-H project within the two involved hospitals. The costs include:

- 2 training course editions for health professionals and hospital volunteers
- 24 monthly project meetings
- Project coordination and management (at least one part-time job for a local coordinator).

Table 10: costs of personnel involved in coordinating and delivery Emp-H (two years).

Activity	costs
Training of health professionals	726€ - 2.382€
Periodical project meetings	2.318€ - 23.271€
Project coordination	31.018€ - 52.048€
<b>Total</b>	<b>From 34.062€ to 77.701€</b>



Concerning the personalized interventions provided within Emp-H, costs considered for the analyses concern the activities related to:

- 1) the profiling activity aimed at identifying behavioural risks in the target groups;
- 2) the counseling session aimed at motivating the target groups to improve behavioural outcomes;
- 3) the provision of additional communication support material.

In Biella the profiling activity was mostly realized by hospital volunteers (eg. in Diabetology, in Cardiology and in Oncology Departments) and by nurses (in Cardiology, in Oncology and in Dietetic Departments). This task was on average 20 minutes long. Then subjects were referred to the Health Promoting Center (HPC) where a 45 minutes psychologist-led counseling session was provided. In addition, it was estimated 15 minutes per person for back-office activity.

In Valencia the profiling activity was performed exclusively by nurses (nurse from Hospital-at-Home service, primary care nurses, and nurses belonging to the Occupational Risk Prevention Area). This task was here estimated to take 20 minutes. The same nurses were then involved in providing a 20 minutes counseling session. Also in this case it was estimated an extra time of 15 minutes per person to organize the entire procedure.

Taking into account the hourly cost of the professionals involved in the counselling activity (table C), and the differences between the two sites in term of time spent to deliver the counselling session and of health professionals involved, it was estimated a **cost between 23.6€ and 32€ per person to deliver the intervention.**

#### **4.4 The health professionals' point of view of Emp-H**

The questionnaire aimed at catching the point of view of health professionals involved in the Emp-H project was filled by 33 persons involved in delivering the intervention (25 from Biella Hospital and 8 from La Fe Hospital). Among these, 17 were nurses, 9 physicians, 4 psychologists, and 3 hospital volunteers (table 11). More than half of participants considered the intervention was more accepted by hospital staff comparing to patients and patients' relatives. The counselling session was in general viewed as accessible for participants and the hospital visit was evaluated as an appropriate opportunity for suggesting health promoting activities, in particular when the target group consisted in hospital workers. Finally, the profiling tool was evaluated as a practical and understandable tool from two thirds of the sample. From the health professionals' perspective, the main barriers for the participants to follow the recommendations provided during the counselling session were:

- 1) lack of time to attend the proposed resources, and
- 2) lack of strategies to face risk behaviour relapses.



Two were the main weaknesses of the Emp-H intervention reported by health professionals:

- 1) lack of continuous support after the counselling session
- 2) lack of contacts with other health professionals (e.g. GPs) that can contribute to reinforce the recommendations provided during the counselling session during the following months.

Table 11. Point of view of health professionals involved in the Emp-H project (n=33)

	Percentage agreement
<b>The intervention:</b>	
was accepted by patients	54%
was accepted by patients' caregivers	45%
was accepted by the hospital staff	66%
was useful in improving subjects' health	75%
was useful in improving care and treatment practices	48%
was useful in improving the work of health professionals	63%
was accessible for participants in terms of:	
time spent to attend the counselling session	93%
effort to attend the workshops and activities proposed by the intervention	93%
reconciliation with other activities (work, family life, leisure time)	81%
<b>The hospital visit is an appropriate opportunity for suggesting health promoting activities:</b>	
to patients?	78%
to patients' caregivers?	78%
to health professionals and hospital workers?	93%
<b>The profiling tool:</b>	
was understandable for the subjects involved in the study	66%
is a practical instrument to facilitate the health professionals activity	63%



## 5 Discussion. Possible implications of Emp-H study

Emp-H is a multi-component intervention including:

- hospital environmental changes,
- recruitment strategy,
- professional-led counseling sessions,
- the maintenance of a network between hospital departments and community institutions that can contribute to sustain the behavioural change.

The introduction of environment changes in the hospital setting (eg. policies, facilities, etc), as well as for the maintenance of a network between the hospital and its catchment area, required an organizational effort and a dedicated allocation of resources. From the observation of what happened in the two organizations involved in Emp-H, it emerges how it is important that within the hospital/health organization a leading team is in force. The leading team could involve representatives from the hospital organizations (management area, health departments, etc.) and/or from the hospital workers (physicians, nurses, other health professionals, staff of the administrative offices, etc.). Regular meetings aimed at organizing environmental changes and agreement with hospital departments and community organizations was provided. An Emp-H team, composed by few hospital representatives with a management role, was also put in force.

Emp-H was able to collect under the same framework different health promoting activities provided by the hospital organization and by the public and private organizations present at community level. This procedure enables the health professionals involved in advising and counselling patients and their relatives to provide a large set of options to change health-related habits. The project was also able to orient the hospital organizations to enforce healthy policies and to promote agreements between hospital departments and community resources. It emerges, therefore, the necessity to allocate adequate investments to enable the hospital organizations to manage health promoting alliances with external resources in their catchment area.

It is possible to notice how Emp-H is an attempt to operationalize the five actions areas for Health Promotion, as stated in 1986 by the Ottawa Charter for health promotion (WHO 1986):

- Build Healthy Public Policies
- Create Supportive Environments
- Strengthen Community Action
- Develop Personal skills
- Reorient Health Services



The Emp-H study tried to decline in the hospital organization these five actions through a randomized controlled trial. The recruitment activity, even if prolonged of two additional months, was not sufficient to engage the expected sample. This difficulty underlines the necessity to adopt higher commitment among hospital departments and to evaluate alternative and more efficient strategies to engage the subjects. Emp-H study teaches that if recruitment is part of a routinely activity (such as the periodically check visit of hospital workers at Occupational Department, or the regular patient's relatives meetings in the Primary Care Centers), the subject engagement tends to increase. Baseline data from the Emp-H study shows how patients, relatives and hospital workers share the same risk factors and the same empowerment level. Patients presented worst outcomes only in BMI and alcohol consumption. This aspect highlights the necessity to invest in the promotion of healthy behavior first at all among health professionals, as they are supposed to be more prone to promote healthy life-styles if they are not implicated with them (Zhu 2011). At the same time, a health professional could constitute with its behavior a role model about correct life-styles among its assisted (While 2015). From our data it was also confirmed that relatives, presenting the same risk factors of the patients, are a special target group as we know that it is difficult to change a behavior if the environment around us is not ready to sustain it (Higgings 2001).

Follow up data demonstrated that the Emp-H intervention was able to improve healthy habits among hospital patients, their relatives and hospital workers, but with differences among the studied behaviors. The greatest improvements were observed for sugary drink intake, excessive alcohol consumption and binge drinking. Better outcomes for smoking cessation and physical activity increase were also observed in the whole sample. This effect, even if biased by other incidental events that could occur during the timespan between intervention and follow up, could be attributed to the brief advice delivered during the consultations and the environmental changes in the hospital setting. One Emp-H hypothesis was that introducing during a routine visit a counseling session, in which the hospital and community opportunities to sustain behavioural change are presented, would have modified risk factors in the target group. Comparing the intervention and the control group, it was possible to observe a further improvement in alcohol and in particular in physical activity outcomes, demonstrating the additional effect of a more intensive intervention, even if sporadic and without additional sessions. These effects could be compared with other previous highly successful lifestyle interventions, like the Diabetes Prevention Program, that obtained a substantial effect in improving lifestyles, but with a greater resource investment (Knowler 2002).

The resources used to put in force the Emp-H intervention in the two hospitals could be considered relatively contained when compared with the impact in term of chronic diseases prevention. This means that an appropriate investment on the organizational framework and on clinical practices in the hospital setting could be repaid with its impact on the population health. Lesson learned from Emp-H study, as well as a literature review on effective health promotion



intervention delivered in the hospital setting, were described in a specific handbook for hospital managers (milestone 9).

From the survey with health professionals involved in Emp-H, emerged further insights about possible development of the Emp-H intervention. Health professionals generally agreed about the acceptability and usefulness of the intervention, but they stated the lack of a support after the discharge. This problem could be overcome by introducing some exchange information system among the professionals in the hospital setting and other health professionals (e.g. GPs or community nurses). Also, the introduction of virtual support, simulating the counselling activity in the period after the counselling session, could reinforce the advices provided by the health professional over time (Kampmeijer 2016).

It is important to note that the data presented should be interpreted in light of several limitations. First the enrollment was not able to recruit the estimated sample. This aspect did not allow us to estimate the effect in the three target groups, and we cannot speculate different effects of the Emp-H intervention among patients, relatives and health professionals. Secondly, it emerged a disproportion between subjects allocated in the intervention group and those assigned in the control group. This aspect was a consequence of the first problem as it was not possible to employ completely the randomization lists. Comparing baseline data among the two groups, it was possible to note no disproportions among the considered variables, so we could consider the two groups as similar. Finally, subjects not attending the counselling session in the intervention group (about 25%) were not contacted at follow up and this aspect could be a source of bias in the results understanding. For this reason, a sensitivity analyses was carried out in order to present the worst-case scenario in which all the subjects didn't change their habits. This analysis allows to interpret conservatively our results.

In conclusion, Emp-H was demonstrated to be a sustainable model able to improve healthy habits among patients, their relatives and health professionals, that could coexist with the actual organization of the European hospitals. Further research could add insights to identify more effective components to improve the model and make it more efficient.



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