

TITLE

Impact on Prehospital Delay of a Stroke Preparedness Campaign: A SW-RCT (Stepped-Wedge Cluster Randomized Controlled Trial)

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Supplementary online content

IMPACT ON PREHOSPITAL DELAY OF A CAMPAIGN AIMED TO INCREASE STROKE PREPAREDNESS: A STEPPED WEDGE CLUSTER RANDOMIZED CONTROLLED TRIAL

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This supplementary material has been provided by the authors to give readers additional information about their work.

METHODS

The campaign development

Published information on factors influencing the prehospital delay and the available evidence on the effectiveness of public education on stroke awareness suggest that simply providing knowledge of stroke symptoms and asking people to call the emergency telephone number for these symptoms is unlikely to be effective (1). Thus, the intervention should target several determinants of behavior, such as stroke recognition skill, self efficacy, outcome expectations and perceived community norms (2). According to the Intervention Mapping framework (3), which recommends that theory and literature evidence be integrated with information obtained from a preliminary context analysis of needs assessment, two surveys were performed, one at the population level (population survey) and the other at patient level (in-hospital survey), which employed evaluation instruments previously published and validated, such as the Stroke Action Test (STAT) to assess stroke awareness in lay people (4,5), and the questionnaire used by Hsia et al (6) to assess the behavioral determinants of stroke patient delay. Besides, the level of health literacy was estimated by a validated screening instrument, the Brief Health Literacy Screen (BHLS), a verbally administered, three-question survey (7-9). The test was properly modified to make it appropriate to the local context. The respondents were asked to answer to three questions: 1. How often do you have someone help you read hospital materials? 2. How often do you have problems learning about your medical condition because of difficulty understanding written information? 3. How often do you have problems learning about your medical condition because of difficulty understanding oral information from medical personnel? The latter question has been changed from the original (How confident are you filling out medical forms by yourself?), because in our context patients are not frequently asked to fill medical forms. Patient responses were recorded in the electronic medical record on a 5-point scale, with e values of 0, 1, 2, 3, 4 and higher scores indicating higher health literacy. According to available evidence, the response cutoff that optimized sensitivity and specificity for low health literacy defined on each question corresponds to a score of 2 (i.e., “some of the time”) on the scale. The two surveys and the intervention development have been extensively described in another paper, still under review.

The preliminary exploratory research confirmed the need for such an approach in our community. Adult individuals, independent of age, sex, education and risk level, were identified as target of the intervention. In fact, findings from our patient survey clearly showed that most patients usually turn to someone else to decide what to do in response to symptom onset and that witnesses of stroke onset can play a central role in the decision-making process. The intervention should therefore target all individuals, not only as potential “patients” but also as potential witnesses of stroke events.

The campaign relied on the following components:

1. Content of the message. It was structured as follows: description of the most frequent symptoms, placing emphasis on the fact that they often are isolated; emphasis on the need that patients call the emergency telephone number immediately, without wasting time by turning to someone else; information on the availability of therapies that can lead to a complete recovery, provided that they are administered early enough.
2. Mode of organizing the message. We used a narrative mode in cartoon form and a series of cartoon characters were featured: the members of a family, including the grandfather as a typical stroke patient, the grandmother, the young nephew and his mother and a super-hero representing the Emergency Medical Services. These characters were embedded into a comic strip, a poster and an animation video. The narrative approach and the use of cartoons were chosen to ensure that people with lower levels of education and lower health literacy could be reached. In fact, according to our exploratory surveys, in the target region education and health literacy levels were comparatively low (eTable1). Notably, among 393 stroke patients and/or their proxies, who were consecutively enrolled into the preliminary in-hospital survey, 55% reported less than high school education, while the correspondent proportion in the general population of Emilia-Romagna aged 15 years and older is 20% (Annual report 2013 of the Italian Institute of Statistics, dati.istat.it). In our sample the proportion of patients with low health literacy was quite high, reaching the percentage of 53% for the question about understanding written medical information. In such contexts, the narrative mode can be most useful. As for the use of cartoons, it has been suggested that visual images in the cartoons, combined with the text, activate different processing systems in the brain, which have been shown to improve understanding (9) and increase recall of medical information (10)
3. Educational products:
 - a. A brochure depicting the comic strip (eFigure 1)
 - b. A poster depicting the super-Hero (eFigure 2)
 - c. An animation video for closed circuits
 - d. An animation video clip for television broadcasting
4. Channels of delivery:
 - a. Mail delivery of the brochures to the households of the participating provinces
 - b. Display of brochures and posters in several public places (hospitals, general practitioners surgeries, malls, pharmacies and headquarters of voluntary organizations)

- c. Broadcasting of the closed-circuit animation video in public places such as the waiting room of the ED.
- d. Broadcasting of the animation video clip on the local television stations.
- e. Putting up exhibit booths for distribution of educational products face-to-face on the occasion of public events, such as street and town fairs, or at weekly markets.

The selection of products and communication channels to disseminate the educational message took into account first of all the results of the exploratory context analysis (eTable 2). Overall, the patient survey suggested that education about stroke through the channels viewed by people as the most reliable, such as the General Practitioner, internet and television, was scarce, so that most of previous information about stroke came through the channel of the inter-personal communication, confirming the high grade of social cohesion and community orientation that is typical of our context. So, the campaign included the message dissemination during public events, viewed as an occasion for supplemental access of people to the message, as well as for face to face consultations with the professionals involved in campaign implementation.

The definitive campaign design had to take into account also the evidence at the time available from literature, which identified as effective on relevant endpoints the home mailing of an educational letter and a multilevel strategy, largely employing mass media.

Finally, methodological and economic constraints, mainly regarding the use of mass media had to be taken into account. Unlike other public health campaigns, television public service announcements were not a primary component of our intervention. This choice was made to prevent contamination between the adjacent provinces involved in the study with overlapping media orbits, in consideration of the stepped-wedge design of the trial.

Four focus groups, one in each province, comprising a convenience sample of patients, relatives, and citizens (from 5 to 8 participants) were conducted to test the educational products and to identify the best channels for distribution in each cluster.

Comparison

According to a preliminary investigation in the 4 participating communities, public education on stroke almost exclusively relies on the initiatives of the Italian Association for Fighting Stroke (Associazione per la Lotta all'ictus Cerebrale, ALICe), such as distribution of educational brochures, meetings with community groups (maximum 4 per year) and screening interventions to identify high-risk individuals (once a year, usually). Mass media, such as television and radio, are not used, except for the broadcasting on the national television of an animation video clip, sponsored by ALICe, on the occasion of the World Stroke Day celebration, once a year.

Definition of clinical characteristics

1. Scores at the National Institute of Health Stroke Scale (NIHSS) at hospital admission.
2. Vascular risk factors and comorbid conditions: hypertension (previous diagnosis, current treatment or blood pressure $\geq 140/90$ mmHg on at least two consecutive measurements); atrial fibrillation (history of chronic or paroxysmal fibrillation, confirmed by at least one ECG or presence of arrhythmia during hospitalization); currently smoking; diabetes mellitus (previous diagnosis, current treatment with insulin, hypoglycemic medications, or fasting glucose levels >126 mg/dl on at least two consecutive measurements); dyslipidemia (previous diagnosis, fasting cholesterol level >240 mg/dl, triglyceride level >200 on a sample taken within 12 hours of hospital admission); clinically evident coronary heart disease (CHD), defined as previous myocardial infarction or unstable angina pectoris, previous or current angina pectoris with objective evidence of atherosclerotic CHD, or a previous coronary revascularization procedure; recent myocardial infarction (within the previous 6 months); previous transient ischemic attack (acute neurological deficit lasting less than 24 hours); significant stenosis ($\geq 50\%$) or occlusion of a major brain artery due to atherosclerosis.
3. The ischemic stroke clinical syndrome, defined in accordance with the Oxfordshire Community Stroke Project (OCSP) criteria (11).
4. The most likely cause of ischemic stroke, according to the Trial of Org 10172 in Acute Stroke Treatment (TOAST) criteria (12)

Sensitivity analysis

As for missing data, the proportion of missing data were 4.3% for the variable NIHSS score and 1.3% for the variable pre-hospital delay within 2 hours. According to the Expectation-Maximization (EM) analysis and Little test, data were missing completely at random ($P 0.621$). and multiple imputation analysis was performed and the missing values were replaced by imputed values from 5 duplicate datasets that were created in order to reduce sampling variability from the imputation simulation. Then, the primary analysis was repeated after exclusion of cases with time onset recorded as a description and on the whole sample, considering two other thresholds (3 and 4 hours) and the delay as a time-dependent continuous variable. In this case, we fitted a log-normal survival regression model with frailty terms shared by inhabitants of the same cluster. The delay was estimated in terms of acceleration failure time and intervention effect was represented as the corresponding time ratio (TmRatio) with 95% confidence intervals (CIs). In the log-normal model, we compared the 2 groups adjusting for NIHSS score at onset, age and calendar time.

Process evaluation

Because of the complex nature of the intervention, a parallel process evaluation was conducted, focusing on two of the key processes that are considered as candidates for examination in any evaluation of cluster trials:

1. Cluster level intervention and variations in its delivery, evaluated through the monthly assessment of the actual delivery of the key components of the educational campaign in each cluster, according to the trial protocol. In particular the dose of the various components actually implemented was registered, such as the number of brochures mailed and the number of posters and brochures displayed in public places.
2. Delivery to individuals and response of individuals, evaluated through a parallel qualitative analysis of interview data about patient experience. Namely, the response to one of the questions of the study interview about the sources of knowledge of stroke was analyzed. The proportion of patients who spontaneously mentioned the campaign as a source of information about stroke was considered as a sensitive index of campaign reach and penetration.

INTERVIEW

Record the source for this case (one answer only, the most prevalent).

- Patient
- Relative who was present at the symptom onset
- Friend who was present at the symptom onset
- If nobody is available to be interview, specify the reason why

Date of the interview*: ___/___/_____ (dd/mm/yyyy)

Starting time of the interview*: __.____ (hh.mm)

Before starting, can you tell me what's your age or your birthday date?

(only if the source is the patient)

Is the answer correct? yes no

Now I am going to ask you questions about the symptoms for which you came to the hospital and how did you get to the hospital

Symptom onset

Date of symptom onset*: ___/___/_____ (dd/mm/yyyy)

- It is possible to record a time

Symptom onset time, as recalled by the patient: _____.____ (hh.mm)

Symptom onset time, as recalled by a bystander: _____.____ (hh.mm)

- It is not possible to record a time

Description*: _____

if the respondent is a relative/friend: Can you describe the symptoms on patient behalf?

Yes NO

Symptom description

	Before hospital admission, which symptoms did you notice	Can you say which one was the very first	And then?	Finally, about what symptom did you worry most?
Numbness or weakness of face, arm or leg - especially on one side of the body				
Confusion, trouble speaking or understanding				
Trouble seeing in one or both eyes				
Trouble walking, dizziness, loss of balance or coordination				
Severe headache with no known cause				
Other (description)				

Reaction of patient /proxy to symptoms

When you developed the symptoms that brought you to the hospital, what did you FIRST think was wrong (record patient/proxy response without prompting)?

- Heart attack
- Stroke
- TIA
- Osteoarthritis
- Dementia
- Other-Please specify: _____
- Didn't know

Where did you learn about the warning signs of stroke . . . anywhere else . . . anywhere else...?" (Record as many as the patient states; do not prompt.)

- Relative/friend had a stroke
- TV
- Radio
- Newspaper or magazine advertisement
- Newspaper or magazine article
- Health fair
- Lecture at Church
- Lecture at Community group
- Lecture at Employer
- Lecture at Nursing home
- Lecture at Health clinic
- (Doctor
- (Don't remember (PROBE: "Any idea where...")
- (Other – Specify: _____

Whom did you first call or speak with after your symptoms started?

- No one/drove to hospital
- 118
- Primary Care Provider
- Relative/Friend
- Other Please specify: _____

What was the reaction of the person you first called or spoke with after your symptoms started?

- Encouraged me to call 911

- Encouraged me to call my PCP
- Encouraged me to go to the hospital
- Drove me to the hospital
- Drove me to a local clinic
- Recommended that I wait to see if my symptoms improved
- Other – Please specify: _____

How did you arrive at the emergency department/hospital (If patient was transferred from another hospital, record the means by which they first arrived for medical attention)?

- Ambulance
- Personal car
- Relative's/Friend's car
- Taxi
- Public transportation (e.g. bus, subway)
- Other - Please specify: _____

Have you had, or has anyone in your family (grandparents, parents, siblings, children) had a stroke?"

- Yes, I had a stroke before
- Yes, someone in my family had one
- No
- Don't know

*On a scale of 0 to 10, how well is your memory today of the events before you reached this hospital? 10 means a perfect memory, and 0 means you do not remember anything?"

Non ricordo nulla	0	1	2	3	4	5	6	7	8	9	10	Memoria perfetta
-------------------	---	---	---	---	---	---	---	---	---	---	----	------------------

*The persons you talked to before you came to this hospital: How serious did they take the signs that something was wrong with you?

- They took it more serious than I did
- I took it more serious than they did
- On balance no difference

* When you first talked with someone that something might be wrong with you, who brought that up?"

- Patient him-/herself
- Another person

*Do you have any handicap that might have slowed down reaching the hospital."

- Yes
- No

(If yes): "Which handicaps do you have in mind?"

POTENTIAL BARRIERS (For patients presenting >3 hours after symptom onset)

What was the reason for delay in coming to the hospital:

(1st ask open ended and write in response(s)): _____
 _____.

Then ask specifically if each of the following was a factor and check all that apply:

- Didn't believe there was anything that could be done to help
- Embarrassed to have ambulance come to the house
- Bad prior experience with hospitals/doctors
- Didn't think symptoms were serious
- Thought symptoms would get better on their own
- Tried to reach my doctor first
- Tried to reach a friend/relative first
- Afraid of hospitals/doctors/tests
- No transportation
- Other – Please specify: _____

PATIENT/PROXY DEMOGRAPHICS

What is the highest grade of education you completed?

- No formal education
- Elementary
- High School
- College
- Graduate Education
- Refused

*Do you live alone?

- Yes
- No
- Refused

PATIENT HEALTH LITERACY*

How often do you have someone help you read hospital materials?				
Always <input type="radio"/>	Often <input type="radio"/>	Sometimes <input type="radio"/>	Seldom <input type="radio"/>	Never <input type="radio"/>

How often do you have problems learning about your medical condition because of difficulty understanding written information?				
Always <input type="radio"/>	Often <input type="radio"/>	Sometimes <input type="radio"/>	Seldom <input type="radio"/>	Never <input type="radio"/>

How often do you have problems learning about your medical condition because of difficulty understanding oral information from medical personnel?

Always <input type="radio"/>	Often <input type="radio"/>	Sometimes <input type="radio"/>	Seldom <input type="radio"/>	Never <input type="radio"/>
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That's all the questions I have -- You've been very helpful. Thank you for your cooperation.

Ending time of the Interview : __ / __ (hh.mm)

Duration of Interview: _____ min

INTERVIEWER SUPPLEMENT

Did respondent request additional health information during this survey?

Yes No

Record respondent questions about survey:

Name and surname of the interviewer _____

Signature of the interviewer _____

*Question for patient only

eTable 1 Characteristics of the participants to the population and in-hospital surveys in terms of demographics, education and health literacy

	Population survey respondents (n=202)	In-hospital survey patients (393)
Age		
M (SD)	51.5 (16.8)	75 (65-83)
Range	18-89	20-100
> 65 % (n)	24 (49)	73 (288)
Gender % (n)	(1 missing value)	
Male	45 (91)	49 (194)
Female	55 (110)	51 (199)
Education % (n)	(4 missing values)	
Primary school (1-5 years) or no education	16 (31)	55 (215)
Secondary school (6-8 years)	22 (43)	24 (94)
High school (9-13 years)	48 (95)	15 (59)
University or graduate education	14 (28)	6 (22)
Low health literacy (Score \leq 2) ^a		
Question1 (N=269)		42 (114)
Question 2 (N= 272)		53(145)
Question3 (N=237)		46 (109)

^aassessed in patients only

eTable 2. Analysis of sources of information about health (population survey) and stroke (in-hospital survey).

	Population survey (202)	In-hospital survey (393)
Options	Question: Which are your preferred and most often used sources of information about health	Question: Where did you learn about the warning signs of stroke ?
Doctor	57 (116)	3.6 (14)
Television	37 (74)	15 (59)
Radio	11 (22)	2 (20)
Newspapers and magazines	24 (43)	9.9 (39)
Internet	45 (92)	1 (4)
Health Association	9.4 (18)	----
Lecture (community group, health clinic) ^a	----	5.8 (23)
Health fair ^a	----	0.5 (2)
Relative/ friend had a stroke ^a	----	52 (203)
Never heard about stroke ^a	----	27.5 (108)
Others	9 (19)	7.4 (29)

^a included in the in-hospital survey interview only

eTable 3. Sensitivity analysis

	Unexposed (710)	Exposed (912)	Effect estimates OR (95% CI)		
Dependent variable	N (%) of patients		Unadjusted	Adjusted for confounders ^a	Adjusted for confounders and other delay determinants ^b
Analysis of the primary outcome (arrival within 2 hours) on multiple imputed data set (pooled estimates)					
Arrival within 2 hrs			0.86 (0.66-1.13)	0.85 (0.64-1.13)	0.87 (0.67-1.14)
Analysis on other definitions of prehospital delay					
Arrival within 3 hrs	412 (58.0)	477 (52.3)	0.86 (0.64-1.12) .27	0.83 (0.63-1.10) .20	0.81 (0.61-1.08) .15
Arrival within 4 hrs	450 (63.4)	539 (59.1)	0.86 (0.66-1.14) .30	0.84 (0.63-1.12) .23	0.87 (0.62-1.23) .43
Arrival within 12 hrs	646 (91)	794 (87)	0.73 (0.48-1.11) .14	0.73 (0.48-1.13) .14	0.76 (0.50-1.16) .21
Analysis on prehospital delay as continuous variable					
Dependent variable			Tm. Ratio (95% CI) P value		
Time interval (minutes)	-----	-----	Unadjusted	Adjusted for confounders ^a	Adjusted for confounders and other delay determinants ^b
	-----	-----	1.12 (0.93-1.34) .23	1.14 0.95-1.36 .16	1.14 0.95-1.37 .15
Analysis after exclusion of stroke onset overnight-on awakening					
Arrival within 2 hours	309 (44.8)	337 (39.1)	0.91 (0.65-1.26) .55	0.90 (0.64-1.25) .52	0.91 (0.65-1.28) .59

^aAge and NIHSS score

^bLiving alone, living in urban areas, diabetes, smoking, atrial fibrillation, TIA, onset overnight-on awakening

e Figure 1

The campaign brochure

ICTUS
RISPARMIA TEMPO
GUADAGNA VITA

PRONTO, 118?
VENITE
SUBITO

HO CHIAMATO
LA NONNA...
E'
ALL'OSPEDALE

IL NONNO
HA AVUTO
UN ICTUS

IL NIPOTINO
E LA MAMMA
SI PRECIPITANO
E...

OSPEDALE

TRANQUILLI...
STO BENE!

E' VERO!
MA COME
HAI FATTO?

IL SEGRETO:
E' SEMPLICE
SE RISPARMI
TEMPO
GUADAGNI
VITA!

NON E' UNA
FAVOLA

SE AVVERTI
UNO O PIU' DI
UNO DI QUESTI
SINTOMI FAI
COME I NONNI

RISPARMIA
TEMPO
GUADAGNA
VITA

CHIAMA
SUBITO IL
118

118

PUOI
RISTABILIRTI
AL 100%!

QUANDO VEDI
IL PRIMO
SINTOMO...

- Perdita di forza al braccio o alla gamba
- Difficoltà a parlare o comprendere
- Bocca "storta"
- Intorpidimento di una parte del corpo
- Difficoltà a vedere in una parte del campo visivo
- Cefalea intensa e insolita
- Vertigini intense con perdita dell'equilibrio

CHIAMA SUBITO
IL **118**!

eFigure 2. The campaign poster

ICTUS

RISPARMIA TEMPO GUADAGNA VITA



**SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
Azienda Unità Sanitaria Locale di Parma
Azienda Ospedaliero - Universitaria di Parma**

Questa campagna, attuata nell'ambito di un progetto di ricerca, è volta ad aumentare nella popolazione di Parma le conoscenze dei sintomi dell'ictus e soprattutto a far comprendere l'importanza di chiamare tempestivamente il 118, per poter ricevere in Ospedale il trattamento ottimale e ridurre mortalità e disabilità.
È UNA CAMPAGNA PROMOSSA DA Regione Emilia-Romagna, nell'ambito del Programma di Ricerca Regione-Università' Bando 2011
È REALIZZATA DA Azienda Ospedaliero-Universitaria di Parma centro di coordinamento dello studio.
CON LA COLLABORAZIONE DI Azienda USL di Parma, Azienda USL di Piacenza, Azienda Ospedaliera di Reggio-Emilia, Azienda USL di Modena.
PER INFORMAZIONI progettoictus@ao.pra.it

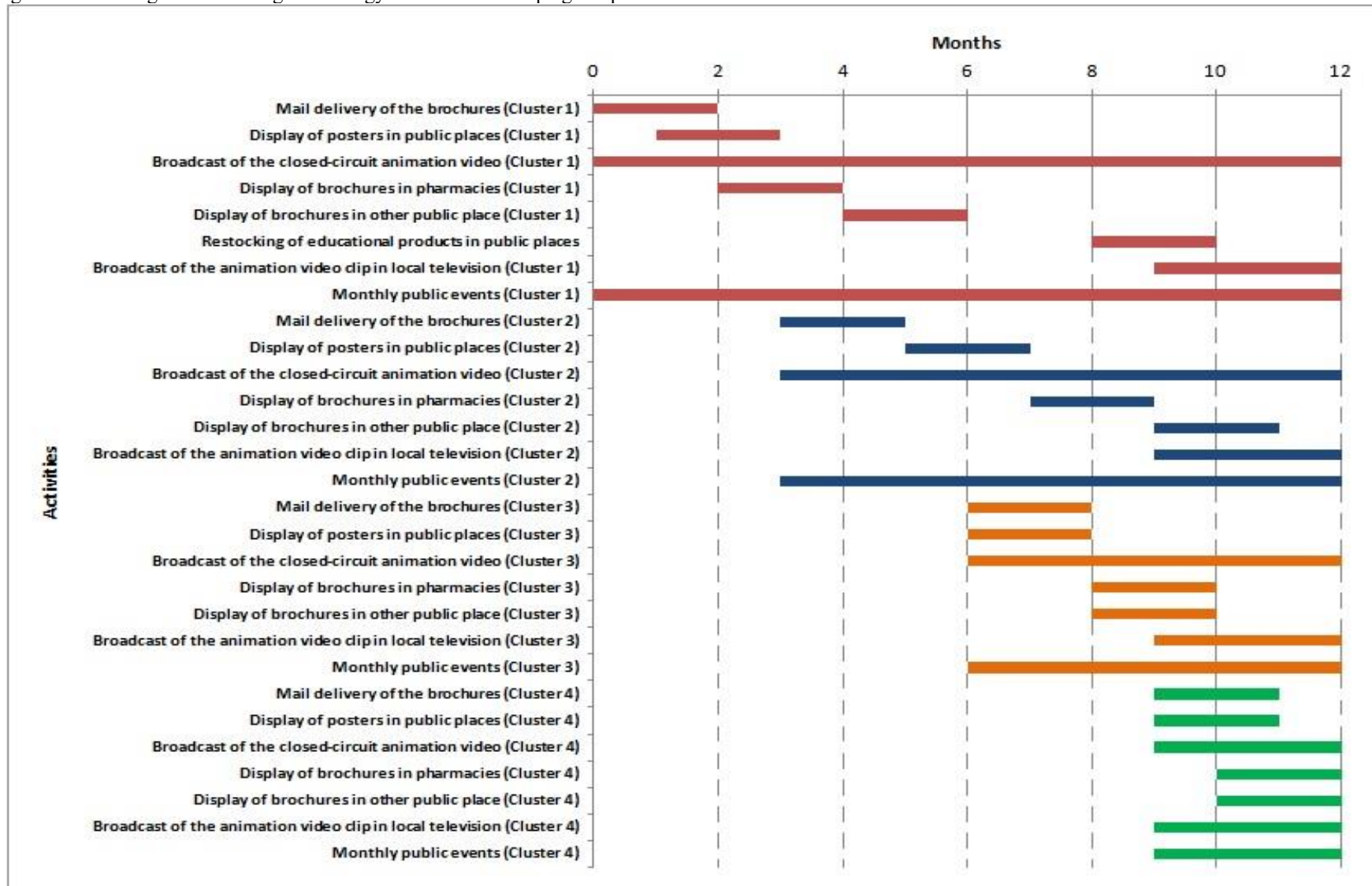
RICORDATI E SINTOMI E NON SOTTOVALUTARLI
Perdita di forza al braccio o alla gamba - Difficoltà a parlare o comprendere - Bocca "storta" - Intorpidimento di una parte del corpo
Difficoltà a vedere in una parte del campo visivo - Cefalea intensa e insolita - Vertigini intense con perdita dell'equilibrio

**Al manifestarsi dei primi sintomi dell'ictus chiama immediatamente il 118
puoi guarire completamente.**

Impara quali sono i sintomi e parlane con amici e famigliari.
I supereroi esistono, soprattutto nella realtà e questa volta puoi esserlo tu.

PASSAPAROLA.

eFigure3. Gantt diagram describing the strategy of the whole campaign implementation



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