

FACULTAT DE MEDICINA DE LA UNIVERSITAT DE GIRONA

CHARACTERIZATION OF CLINICAL
AND ELECTROCARDIOGRAPHIC
FINDINGS IN A YOUTH POPULATION

FINAL PROJECT

Author: Pau Vilardell Rigau
Tutor: Ramon Brugada Terradellas



13/11/2013

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ORIGINAL ARTICLE

TITLE: Characterization of clinical and electrocardiographic findings in a youth population

Vilardell P. MS, Brugada R. MD PhD, Falces C. MD PhD, Puigdevall Ma. MD, Brugada J. MD PhD

ABSTRACT

Introduction: Resting 12-lead electrocardiogram (ECG) has been employed in the evaluation of young asymptomatic subjects to detect pre-existing heart diseases. Although the incorporation of routine ECG remains controversial, there is increasing evidence that cardiomyopathies and ion channelopathies show ECG changes as the initial manifestation. The causes of sudden cardiac death in young people show a significant geographical variation. We aim to determine the prevalence and spectrum of ECG findings in a youth population.

Methodology: From May 2010 to April 2013, a total of 976 young secondary school students (mean age, 14 years; range, 13-15) underwent voluntary medical screening that included a resting 12-lead ECG and structured clinical survey. Subjects with abnormal ECG findings were classified into two groups: major ECG findings group, which fulfilled a pre-specified checklist to screen for principal structural and electrical cardiopathies, and minor ECG findings group showing other ECG changes. The major ECG findings group was referred for secondary diagnostic tests at a tertiary institution.

Results: Of the 976 subjects screened, 252 (25.82%; CI95%, 23.17-28.66) had ECG findings. Of note, 17 (1.74%) had major findings and 235 (24.08%) had minor findings on ECG. The prevalence of cardiovascular pathology within the major ECG findings group was 35.29%. The prevalence of ECG abnormalities was significantly higher in males than in females (29% vs 20.9%, $P<0.01$).

Conclusions: The prevalence of ECG findings in a youth population was 25.82%. There were significant gender differences. The inclusion of universal ECG screening, in addition to medical history, may increase the sensitivity of a cardiovascular screening program. Knowledge of the spectrum and prevalence of ECG findings and disease conditions would be pivotal in designing customized screening programs.

Keywords: Mass screening, ECG findings, youth population, sudden cardiac death, clinical survey

1- INTRODUCTION

1.1- Background

Most males and females between 13 and 15 are healthy. These teenagers have undergone regular pediatric controls by the National Health System (NHS). However, given that in this population a 12-lead electrocardiogram (ECG) and a cardiac clinical history are not universally recorded, clinical and/or electrocardiographic findings are not documented in a healthy young population.

There are heart diseases that can cause symptoms such as palpitations, loss of consciousness and sudden cardiac death in the young population. Sudden cardiac death is the most important clinical manifestation due to the large impact that entails. It is defined as an unexpected natural death by cardiac causes, heralded by abrupt loss of consciousness during the early acute symptoms¹⁻³. When this happens, it is devastating for the family and social environment of the patient, because young people are the healthiest stratum of the general population⁴⁻⁶. Although the incidence of sudden cardiac death in young people is not well established, it is estimated to range between 0.8 and 3.8 per 100.000 person-year^{1,5-8}. The strongest evidence is provided by a prospective observational study from the region of Veneto (Italy), where an incidence of 2.3 per 100.000 person-year (2.6 in males / 1.07 in females) was reported^{7,9}. Most of these epidemiological studies are based on the athletic population, because the risk of sudden death is higher in this population compared to non-athletes^{10,11}. Recently, Marijon et al have reported that the increase of relative risk in sport-related sudden cardiac death in high performance athletes (10-35 years) compared with non-competitive athletes of the same age is 4.5 times higher¹². About 25% of sudden cardiac deaths in young people occurs during the sports activity^{13,14}.

Being male is a well-known independent risk factor for sudden cardiac death, both in general population, where there is a 3:1 ratio, and in young athletes population, where the ratio is even higher (9:1)^{2,4-6,11,15}.

Most sudden cardiac deaths in young people are secondary to pre-existing cardiovascular disease⁵. The prevalence of cardiovascular disease in young athletes is 0.3%¹⁶. These underlying cardiovascular diseases associated with sudden cardiac death are classified into three groups^{5,7,11,15}:

- *Electrical cardiac abnormalities*, including Wolff-Parkinson-White syndrome (WPW), Brugada syndrome (BrS), long QT syndrome (LQTS) and short QT syndrome (SQTS).
- *Structural cardiac abnormalities*, mainly including hypertrophic cardiomyopathy (HCM) and arrhythmogenic right ventricular dysplasia (ARVD), but also Marfan syndrome, congenital anomalies of the coronary arteries, mitral valve prolapse and aortic stenosis have been reported.
- *Other acquired cardiac abnormalities*, including myocarditis and premature atherosclerotic coronary artery disease, among others.

The causes of sudden cardiac death in young people have shown a significant geographic variation. While in Italy the leading cause of sudden cardiac death among young athletes is ARVD, in the U.S. the main cause is HCM^{14,17-20}. These cardiac diseases aforementioned usually remain asymptomatic and therefore often go unnoticed. So, it is necessary to use diagnostic tests that allow us to identify those patients with a risk of sudden cardiac death predisposition within an apparently healthy population.

The baseline 12-lead ECG can orientate the diagnosis of most of cardiac diseases listed above. This test has shown high sensitivity and specificity for the detection of these cardiac diseases in populations of young individuals^{8,10}.

About 95% of individuals with HCM and 80% of patients with ARVD showed electrocardiographic findings. As for individuals with LQTS, electrocardiographic findings are identified with a 12-lead ECG in 85-90% of these patients²¹⁻²³. The baseline 12-lead ECG is a test with a high negative predictive value (99.98%) and, therefore, excludes pre-existing cardiovascular diseases if normal¹⁰. A common objection to this diagnostic test is the supposed high rate of false positives, resulting in unnecessary additional investigation tests. It should be noted that this false positive rate is largely determined by the criteria used to define the electrocardiographic abnormality¹⁰. Thus sense, the current recommendations of the European guidelines for interpretation of the electrocardiogram have eliminated the isolated voltage criteria for left ventricular hypertrophy (LVH) as a criteria which requires additional diagnostic evaluations, thus reducing the false positive rate^{10,24-26}.

Corrado et al have compiled a table that correlates the most frequent pre-existing cardiovascular diseases and their associated electrocardiographic findings in athletes⁸. The electrocardiographic screening together with a structured survey for clinical data in large populations conducted in several countries has proved useful for identifying young asymptomatic people with pre-existing cardiac diseases^{9,27}.

It has been shown that electrocardiographic screening is more sensitive than clinical history and physical examination to identify patients at risk of sudden cardiac death^{28,29}. Corrado et al have reported that the 12-lead ECG has 77% more chances to detect HCM than the clinical history and physical examination³⁰.

Only 7% of young individuals with sudden cardiac death had a positive family history, and in <1% of those the anamnesis and physical examination confirmed the diagnosis of sudden cardiac death³¹.

The implementation of electrocardiographic screening program prior to sports activity has resulted in a 89% reduction in the annual incidence of sudden cardiac death (3.6 per 100.000 person-year in the pre-screening stage to 0.4 per 100,000 person-year at present) in the Italian region of Veneto^{6,8,19,20,30,32}. The electrocardiogram screening in young adults have demonstrate that is cost-effective in multiple studies^{8,10,28,30,33}. Recently, Lesslie et al have reported that performing an electrocardiogram screening for young people of 14 years old is cost-effective^{14,31}.

1.2- Justification of the project

The prevalence of symptoms and electrocardiographic findings in young people is unknown especially because it occurs in the healthiest stratum of the population. We believe that conducting 12-lead ECG universally in males and females between 13 and 15 years, in combination with a structured clinical survey will allow (i) determining the prevalence of electrocardiographic and clinical findings that can warn on the possibility of underlying cardiovascular disease, (ii) characterising the main electrocardiographic findings and clinical manifestations of this population and (iii) establishing early diagnosis of potentially serious pre-existing cardiovascular diseases.

Furthermore, the impact of sudden cardiac death, while statistically small, has an effect greater than other causes of death, mainly on the family and social relations of the victims. This is due to the apparent suddenness and unexpectedness in an individual who was previously considered in the best of health and consequently in no danger.

In conclusion, we considered that further studies on this subject are more than justified.

2- HYPOTHESIS

Mass screening for young people aged between 13 and 15 years, consisting of an electrocardiogram and a structured clinical survey, would allow early identification of electrocardiographic findings and/or symptoms in this population. The characterization of these findings will identify the prevalence of those in the population studied and those suspected of pre-existing cardiovascular disease. Because most of these underlying cardiovascular pathologies are asymptomatic, we expect to find a higher percentage of electrocardiographic abnormalities than clinical alterations. According to the studies cited in the bibliography, we hope to find a greater number of electrocardiographic abnormalities in males.

A more comprehensive cardiac study of patients with major electrocardiographic findings and/or suspected heart disease by clinical history collected through structured survey would permit early detection of underlying cardiovascular diseases.

The data obtained from the structured clinical survey and electrocardiography could be related to see potential associations. We would hope to find associations between electrocardiographic findings and other variables: gender; family history of sudden cardiac death; and clinical history of palpitations, loss of consciousness, seizures and chronic medication.

3- OBJECTIVES

Principal objective

- To ascertain the prevalence of clinical and electrocardiographic findings in a general healthy population between 13 and 15 years.

Secondary objectives

- To ascertain the prevalence of pre-existing cardiovascular disease in patients with major electrocardiographic findings and/or suspected cardiovascular disease by clinical history collected through structured survey.
- To analyse the association between electrocardiographic findings and clinical characteristics, as well as the association between electrocardiographic findings and gender.

4- MATERIALS AND METHODS

4.1- Study design

This report is based on a pilot project started in May 2010 in the Pla de l'Estany county. The whole project was divided into two phases: the first phase consisted of a descriptive cross-sectional population-based study where an electrocardiographic screening was carried out to identify the main clinical and/or electrocardiographic findings of the sample group. In all participants it was required a signed parental consent form before participating. (This document is shown in *Annex 1* [parental consent form]). The second phase consisted of a prospective follow-up of those individuals identified with relevant clinical history and/or major electrocardiographic findings.

This project was approved by the Ethics Committee of Clinical Research (CEIC) of the Hospital Clinic of Barcelona. (See in *Annex 2* [resolution of Ethics Committee]). Participation in the project was entirely voluntary and each individual was able to drop-out or reject their involvement in the study at any time of their choosing. The decision to participate or not will not influence the quality of medical care that every individual is entitled to receive. Electrocardiograms and clinical surveys were coded to ensure the protection of the identity of individuals. The researchers who analyzed study variables were blinded to the personal data of participants.

The researchers were committed to follow the ethical principles established in the Declaration of Helsinki³⁴. Likewise, the research team was committed to ensure compliance with the principles set out in the Llei Orgànica de Caràcter Personal 15/1999 and to facilitate their rights of access, rectification, cancellation and opposition to the data and/or electrocardiograms.

4.2- Study population

The study population was made up of young people registered during the 2nd year of obligated secondary education (ESO) in secondary schools of Pla de l'Estany county, in the academic years from 2009/2010 to 2012/2013. Along this period, 1.212 students were enrolled in these secondary schools. The centers of Pla de l'Estany county are: secondary schools of Pere Alsius i Torrent, Josep Brugulat, Pla de l'Estany and Casa Nostra.

4.3- Sampling

The research team for this study used a non-probabilistic volunteer sample. All 1.212 students enrolled in secondary schools of Pla de l'Estany county were the target population, and we aimed to obtain a minimum of 70% participation of that population to get a representative sample.

4.4- Instrumentalization and study variables

The material used for the study was:

- Laptop with a USB extension composed of 10 electrodes, a processor which detects and transmits the electrical information of the heart, and specific software that record the electrocardiograms, called CardioSoft ®. Along these four years, the same computer laptop from the medical school of University of Girona (UdG) has been used to perform the ECG recording.
- 10 patches / volunteer with alcohol and swabs to attach the electrodes to the specified parts of the body of the young people.
- Paper, ink and envelopes for briefing documents by the project, parental consent form, clinical surveys and medical reports to give to each individual.

The variables studied were:

Outcome

- Electrocardiographic findings
 - Major electrocardiographic findings: significant findings requiring additional cardiac follow-up to rule out underlying cardiovascular disease. (These electrocardiographic findings are summarized in *Table 1*)
 - Minor electrocardiographic findings: findings without pathological significance or that are simply variants of normality. (See in *Table 1*)

Associated variables o covariates

- Date of birth
- Sex: male / female
- Electrocardiographic measurements:
 - Heart rate: number of beats per minute
 - QRS: duration of QRS complex in milliseconds (ms)
 - QT: duration between Q wave and T wave in ms
 - QTc: corrected QT segment according Bazzett formula ($QTc = QT/\sqrt{RR}$)
 - P: duration of P wave in ms
 - PR: duration between P wave and R wave in ms
 - RR: duration between R waves of different QRS complexes in ms
 - PP: duration between P wave of different QRS complexes in ms
- Medical history: clinical data recorded using a structured survey based with *12-Point AHA Questionnaire*²⁰. Family history of sudden cardiac death, medical history of palpitations, loss of consciousness, seizures and chronic medication were asked in the structured survey. (See *Annex 3* [structured clinical survey]).

4.5- Methodology

Every student of 2nd ESO in Pla de l'Estany county received a letter with a synopsis of the project, a parental consent form and a clinical survey which assessed personal and family medical history of the individual. These documents are shown in *Annex 1* [parental consent form] and *Annex 3* [structured clinical survey]. The letter was sent by the tutors of the different secondary schools of Pla de l'Estany county.

The Educational Department of the City of Banyoles coordinated the timetable of all secondary schools with the medical team, consisting of two nurses and two medical students to visit each school in accordance with their regular timetable. (See in *Annex 4* [work schedule]).

On day of visit to the school, each student had a signed parental consent form and filled out the clinical survey. The medical team reviewed the clinical survey answers and performed a 12-lead resting ECG, that was recorded in supine position, according good clinical practice recommendations for performing electrocardiograms³⁵. All ECG were recorded at the different secondary schools of Pla de l'Estany county. Only these ECG that the researchers considered low-quality ECG were repeated at the primary health center of Banyoles.

The electrocardiograms were analyzed initially by the student researcher (PV) and were reviewed in their entirety by a cardiologist (JB) with extensive experience in pediatric cardiology. Only if the researchers identified a major electrocardiographic finding and/or suspected heart disease by clinical history collected through structured survey, a more comprehensive cardiac study of these patients were performed in a tertiary center by a specialized clinician (MaP). Additional diagnostic tests were requested according hospital's clinical practice guidelines. (See flowchart of the ECG screening in *Figure 1*).

4.6- Electrocardiographic measurements

All electrocardiograms were recorded digitally by the program CardioSoft ® from a laptop provided by the medical school the UdG. All participants' data were introduced in the program CardioSoft ® with a randomized code. During the recording electrocardiograms were kept with EXA format. These documents were transformed into PDF format to perform the analysis and electrocardiographic study variables were entered in a database in Excel format. The variables entered in the database were as follows:

- Identifying data : code ID / date of birth / gender
- Electrocardiographic variables: heart rate (bpm) / QRS (ms) / QT (ms) / QTc (ms) / P (ms) / RR (ms) / PP (ms) / PR (ms) / electrocardiographic findings (See in *Table 3*).
- Clinical data: family history of sudden cardiac death / medical history of palpitations, loss of consciousness, seizures and chronic medication.

To facilitate the analysis, electrocardiographic findings were divided into two categories: major findings and minor findings. *Table 1* shows the ECG findings were included in both groups. This classification rely on recommendations of the European Society of Cardiology (ESC)^{7,8,24}. All electrocardiographic variables were continuous variables, and all clinical variables were dichotomous variables. About the electrocardiographic findings (outcome of the study) was a categorical variable (normality, minor electrocardiographic finding and major electrocardiographic finding).

4.7- Statistical analysis

The estimated prevalence of electrocardiographic findings in the study population was ascertained with a confidential interval of 95%. Also, a confidential interval of 95% was used to ascertain the prevalence of underlying cardiovascular disease on patients with major electrocardiographic findings and/or suspected cardiovascular disease by clinical history collected through structured survey.

All electrocardiographic variables were considered continuous variables. We estimated the average, standard deviation, maximum value and minimum value of each electrocardiographic variable. (See in *Table 2*).

A binary logistic regression model to assess the association between the outcome (electrocardiographic findings) and associated variables (family history, history of palpitations, loss of consciousness, chronic medication and sex) was used for statistical analysis.

To facilitate the analysis, the response variable was grouped as if it was a dichotomous variable (electrocardiographic findings vs normality). All associated variables (clinical data and gender) were also treated as dichotomous variables.

In statistical analysis we used the Wald contrast. Moreover, the estimated odds ratios (OR) were calculated for each covariate and their 95% CI. In this study, those variables statistically significant were considered if p value <0.05. The statistical package used in this study was SPSS.

5- RESULTS

5.1- Demographic data

Total participation in our study was 80.53% (976 individuals). The participation of enrollment by years and sex is shown in *Table 3*. As for students who did not participate, only 12 individuals (0.99% of the total population) replied formally in the negative with the parental consent form. The remainder (94.95% of students who did not participate in the study) did not reply formally with the parental consent form.

According to gender variable, rates of enrollment were 50.61% for females (n = 494) and 49.39% for males (n = 482). (See in *Table 3*).

5.2- Clinical data

A total of 222 individuals (22.75%) reported a positive family history in the structured clinical survey. In the section on personal history: 160 individuals (16.39%) reported palpitations, 105 individuals (10.76%) had a clinical history of loss of consciousness, and only 18 (1.84%) had experienced seizures. 9.32% of the study population (91 individuals) reported that they were using some kind of chronic medication. The most common chronic medication included:

- Respiratory disorders: 45 individuals (4.61%)
- Attention deficit hyperactivity disorder (ADHD): 18 individuals (1.84%)
- Thyroid-related disorders: 6 individuals (0.61%)
- Diabetes mellitus type I: 4 individuals (0.41%)

5.3- Electrocardiographic findings

Electrocardiographic findings were identified in a total of 252 individuals (25.82%) (23.17, 28.66 95% CI). Of these, 235 patients (24.08%) showed minor electrocardiographic findings and only 17 patients (1.74%) showed major electrocardiographic findings requiring additional diagnostic tests in a tertiary institution.

The average heart rate of the target population was 80.07 bpm, with a maximum value of 143 bpm, minimum value of 44 bpm and standard deviation of 15.24. (*Table 2* summarizes all ECG variables). About the minor electrocardiographic findings, the third most frequent were isolated QRS voltage criteria for left ventricular hypertrophy (6.05% of sample population), sinus bradycardia (5.53% of sample population) and early repolarization (2.97% of sample population). These three common abnormalities included more than 60% of all minor electrocardiographic findings. (*Table 2* shows all ECG findings).

Of the 17 individuals with major electrocardiographic findings, additional tests showed that 6 of those patients (35.29%) (17.31, 58.70 95% CI) had been diagnosed with pre-existing cardiovascular disease. These underlying cardiovascular pathologies were: a bivalve aortic valve, a coronary fistula without hemodynamic repercussion, a mitral valve prolapse, two bifascicular blocks and a patient with criteria of left ventricular hypertrophy, right bundle branch block (RBBB) and short PR interval. (See in *Table 4*).

In conclusion, pre-existing cardiovascular diseases were identified in 0.61% (0.28, 1.33 95% CI) of the target population.

5.4- Statistical analysis results

The prevalence of electrocardiographic findings was significantly higher in the group of males where the prevalence was 29%, compared to the female group where the prevalence was 20.9%. This association was statistically significant (p value = 0.003). The estimated odds ratio (OR) of this covariate was 1.554 (1.159, 2.083 95% CI).

No significant associations were found in other covariates, see in *Figure 2. Table 5* show detailed statistical analysis of the other covariates.

6- DISCUSSION

6.1- Previous studies and interpretation of the results

The main observation of this pilot study is that the prevalence of electrocardiographic findings is 25.82% in this healthy youth population. However, only 17 (1.74%) required additional diagnostic tests because they had shown major electrocardiographic findings and/or suspected cardiovascular disease through clinical history collected in structured survey. Differences of the target population and the methodology of the study could explain the disparity of the results if it is compared with other similar studies: the ECG screening in trained athletes was performed by Italian researchers, and showed cardiovascular remodeling associated with ECG abnormalities as frequently (up to 80%) and the uncommon ECG patterns in <5%²⁶. In contrast, the Japanese studies demonstrate ratios of cardiovascular pathologies between 0.01-0.04% in pupils and students, lower than in the Pla de l'Estany county study^{27,29}. In accordance with references, ECG findings are especially frequent in the male gender^{2,4-6,11,15}.

In mass screening for heart diseases, it has often been found difficult to judge immediately as to whether or not young adults need medical management when they have ECG findings. Although most these ECG changes are 'abnormal' in a strict statistical sense, they do not imply the presence of cardiovascular disease or an increase of cardiovascular risk and sudden cardiac death in young adults.

Underlying cardiovascular diseases found in our study were not the most frequent as described in the previous references. While in Italy the leading pre-existing cardiovascular disease in young athletes is ARVD, in the U.S. the main cause is HCM^{14,17-20}. Geographic variations could explain these results.

A curious data found in our study was that 52.94% of major electrocardiographic findings were identified in the last year of the study (2013). We attributed these results as random, because we used same materials, medical team and criteria at the reviewing of 12-lead ECG for referral to a specialized clinician during the years of the study.

To our knowledge, this study is the first to investigate electrocardiogram findings and clinical data universally in a healthy young population between 13 and 15 years.

6.2-Strengths and Limitations

A high-level participation of 80.53% was obtained. This high participation rate suggests that the sample population is similar to the population studied.

The low prevalence of structural and electrical cardiopathies that cause sudden cardiac death in this population has been one of the most important limitations of this project.

A common limitation of ECG screening is the high rate of false positives, which entails unnecessary additional diagnostic tests. It was attempted to solve this problem using the criteria of electrocardiographic findings modified from Corrado et al⁸. These criteria show clearly which electrocardiographic findings needs additional diagnostic tests and which electrocardiographic findings do not. This classification of ECG findings reduces patients that have to visit a tertiary institution without pathology, and thereby also reducing concurrent family anxiety.

One of the problems with the screening system is the reliability of the information obtained from questionnaires. Secondary school students often answer the questions by themselves without consultation with their parents thereby reducing the reliability of the questionnaires²⁷. It was attempted to solve this problem by requiring the signature of student's parents in the questionnaires which were then checked before ECG recording.

6.3- Clinical implications

The addition of universal ECG screening in combination with a structured clinical survey may increase the ability to detect people at risk of sudden cardiac death and to meet the primary objective of the screening evaluation: detection of those at risk of sudden cardiac death, with the hope of decreasing morbidity, mortality, and/or disease progression through early detection, early intervention, and appropriate management.

7- CONCLUSIONS

The prevalence of electrocardiographic findings in a population of young adults between 13 and 15 years old was 25.82%.

The prevalence of cardiovascular pathology within the group of patients with major electrocardiographic findings was 35.29%.

There is no association between the outcome (ECG findings) and clinical variables such as palpitations, loss of consciousness, family history of sudden cardiac death and chronic medication. We have found statistically significant association between the outcome (ECG findings) and variable gender. Males are 1.554 times more likely to have electrocardiographic findings than females.

8- CONFLICT OF INTEREST STATEMENT

None declared.

9- ACKNOWLEDGEMENTS

The authors would like to thank all participants for their willingness to contribute to this study and all field-personnel for their commitment and quality of their work. Specifically, the medical team composed of four nurses (M^aLourdes Coll Xargay, M^a Angels Bosch Juscafresa, Montserrat Frigolé Vila and M^a Teresa Garcia Hermandó), a medical student (Raquel Bosch Compte) and a pediatric cardiologist (Ma Àngels Puigdevall).

Furthermore, I would like to express gratitude for the revision of the work of the tutors Dr. Carles Falces and Dr. Ramon Brugada. Their review has been essential for the quality of this work.

Finally, I would like to thank Dr. Josep Brugada for his leadership in this project that has been indispensable in achieving the objectives set.

Moreover, I would like to express gratitude for the support received by Ajuntament de Banyoles, Facultat de Medicina of UdG, Hospital Clínic de Barcelona and Fundació Pascual i Prats of Col·legi Oficial de Metges de Girona (COMG).

10- BUDGET

The budget was divided into three sections: personal expenses, costs of implementation and travel & subsistence. Personal expenses were covered by Ajuntament de Banyoles, costs of implementation by Facultat de Medicina of UdG and Fundació Pascual i Prats of COMG, and travel & subsistence by Hospital Clínic de Barcelona.

1.- Personal expenses

Part time nursing services recruitment	
1 st annuity	800€
2 nd annuity	800€
3 rd annuity	800€
4 th annuity	800€
SUBTOTAL	3.200 €

2.- Costs of implementation

Acquisition of inventory and service contracts	
Computer laptop	1.500 €
Other consumable material	500 €
Statistical Analysis	800 €
SUBTOTAL	2.800€

3.- Travel & subsistence

Attendance at a national conference	1.000 €
Attendance at an international conference	2.000 €
SUBTOTAL	3.000€
TOTAL	9.000 €

11- TABLES AND FIGURES

Table 1: Classification of electrocardiographic findings

MINOR ECG FINDINGS	MAJOR ECG FINDINGS
First degree AV block	ST-T abnormalities
Sinus bradycardia	Pathologic Q waves
Isolated QRS voltage criteria for LVH	LBBB
Early repolarization	Complete RBBB
Axis deviation (Axis QRS $<30^\circ$ or $>120^\circ$)	Ventricular premature beats
Incomplete RBBB	QT interval abnormalities
Left atrial enlargement	More than 1 minor ECG findings
Atrial premature beats	

Modified from Corrado et al (8). AV= atrioventricular / LBBB=left bundle branch block / LVH=left ventricular hypertrophy / RBBB=right bundle branch block.

Table 2: Electrocardiographic variables and findings

<u>ECG variables</u>	<u>Average</u>	<u>Standard deviation</u>	<u>Max. value</u>	<u>Min. value</u>
QRS	89,25 ms	11.65	126 ms	62 ms
QT	361,68 ms	32.80	464 ms	266 ms
QTc	412 ms	30.10	530 ms	296 ms
P	85,75 ms	12.1	128 ms	45 ms
PR	136,2 ms	20.37	294 ms	88 ms
RR	765,6 ms	153.94	1384 ms	422 ms
PP	765,07 ms	152.56	1360 ms	415 ms

MINOR ELECTROCARDIOGRAPHIC FINDINGS

<u>ECG Findings</u>	<u>n</u>	<u>Percentage</u>
1 st Degree AV Block (PR>200ms)	11	1.13%
Sinus bradycardia (<60 bpm)	54	5.53%
Early repolarization	29	2.97%
Axis deviation (Axis QRS <30 o >120)	27	2.77%
Incomplete RBBB	13	1.33%
Left atrial enlargement	21	2.15%
Atrial premature beats	21	2.15%
Isolated QRS voltage criteria for LVH	59	6.05%

MAJOR ELECTROCARDIOGRAPHIC FINDINGS

<u>ECG Findings</u>	<u>n</u>	<u>Percentage</u>
ST-T abnormalities	2	0.21%
Ventricular premature beats	2	0.21%
LBBB or complete RBBB	2	0.21%
QT interval abnormalities	2	0.21%
More than 1 minor ECG findings	9	0.92%

AV= atrioventricular / LBBB=left bundle branch block / LVH=left ventricular hypertrophy / RBBB=right bundle branch block.

Table 3: Annual percentage by years of enrollment and gender

<u>Years of enrollment</u>	<u>Nº of participants</u>	<u>Participation (%)</u>	<u>Males</u>	<u>Females</u>
2010	254	92,36%	135 (53.15%)	119 (46.85%)
2011	244	74,84%	118 (48.36%)	126 (51.64%)
2012	245	78,53%	115 (46.94%)	130 (53.06%)
2013	233	77,93%	114 (48.93%)	119 (51.07%)
Total	976	80,53%	482 (49.39%)	494 (50.61%)

Figure 1: Flowchart of the electrocardiographic screening

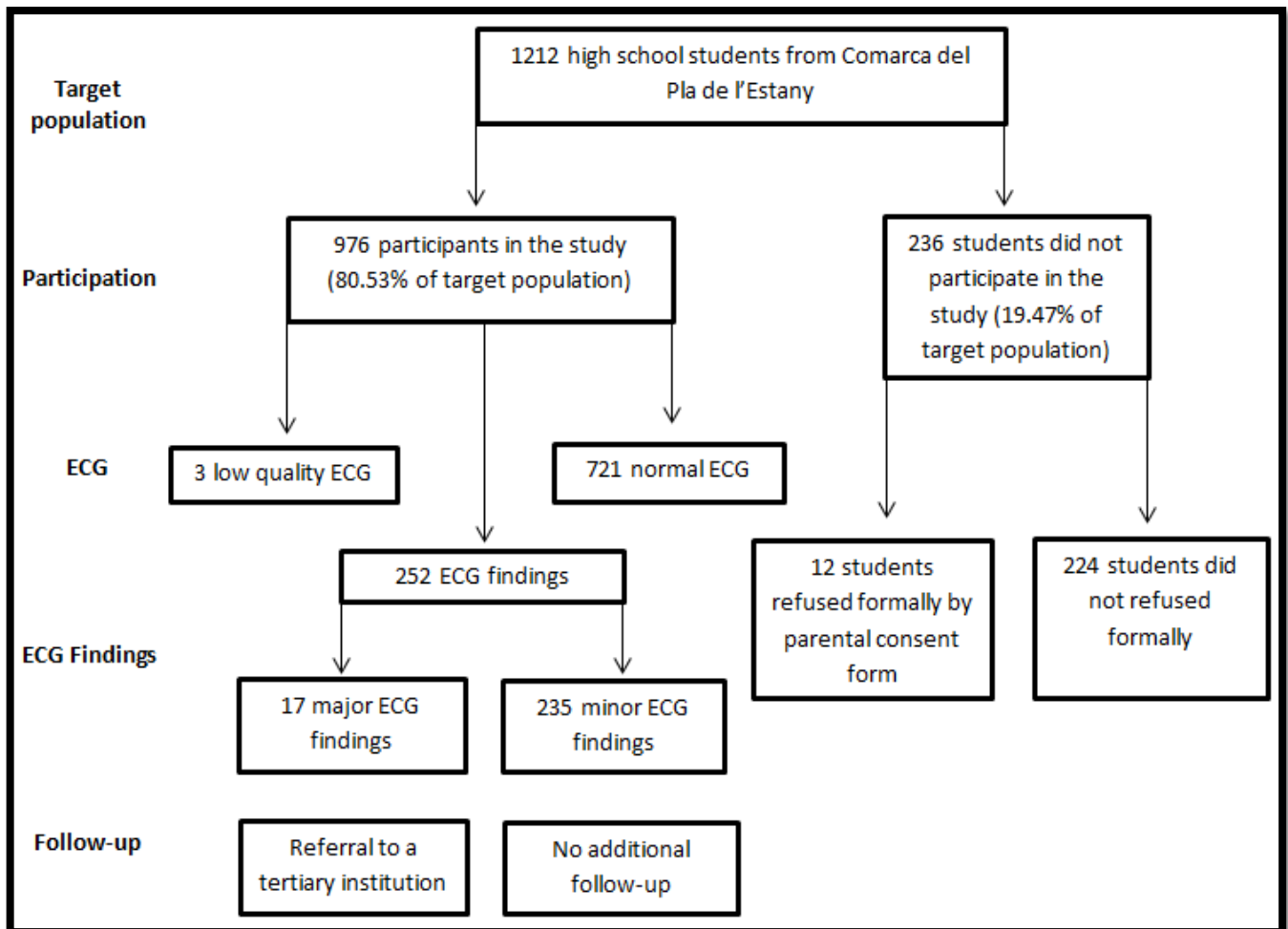


Table 4: Patients with major ECG findings

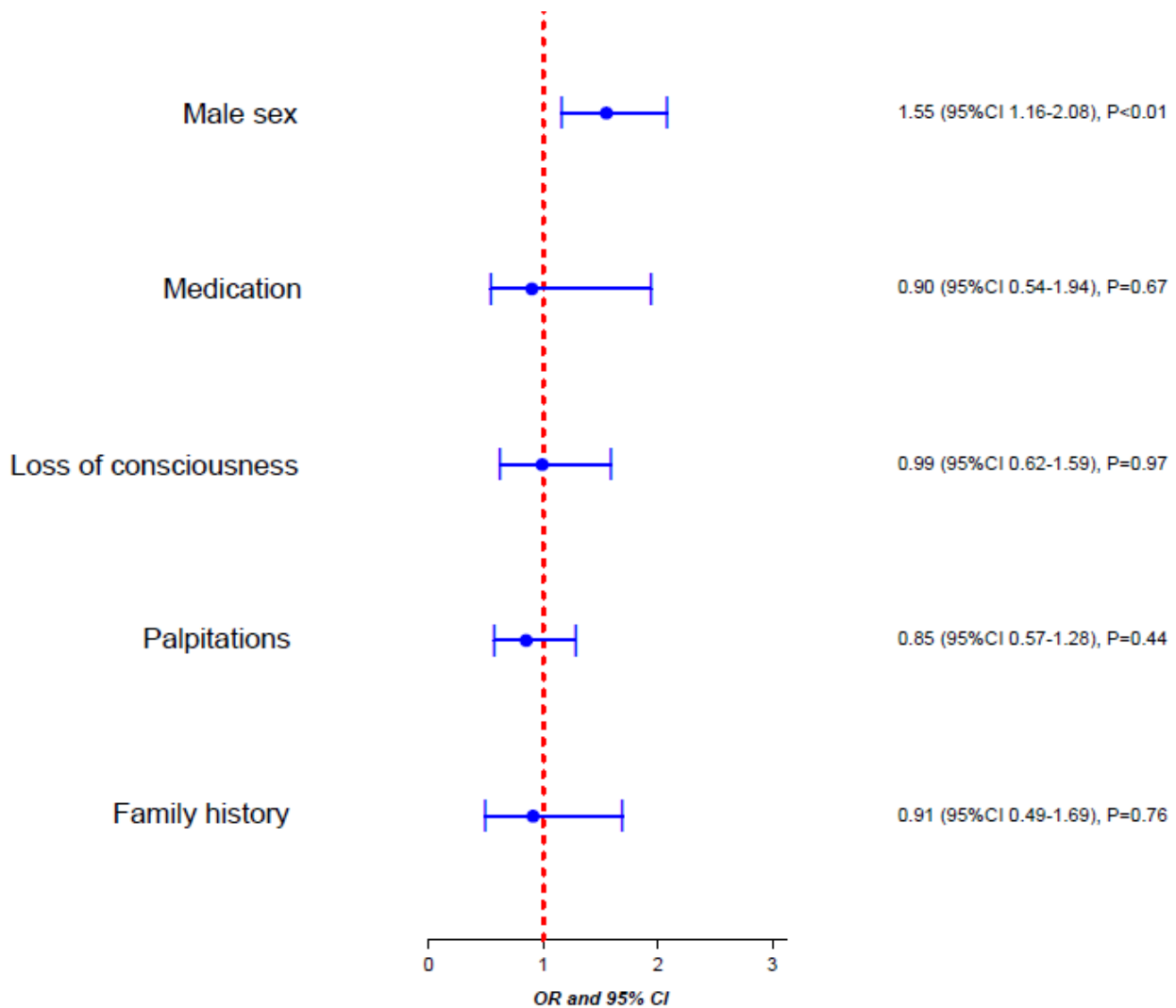
YEAR	CODE	MAJOR ECG FINDINGS	DIAGNOSTIC TESTS	DIAGNOSTIC	FOLLOW-UP
2010	7474	Incomplete LBBB	ECG/ECO-Doppler	No structural cardiopathy	Discharge
	2516	Rhythm abnormalities	ECG/ECO-Doppler	SR altering atrial rhythm	AC
	1489	Multiple VPB	ECG/ECO-Doppler Holter 24 h/ EST	Isolated VPB, mild AR with bivalve aortic valve	AC
2011	27438	ST-T abnormalities	ECG/ECO-Doppler / Holter 24 h/ EST / MRIc	Coronary fistula without hemodynamic repercussion	AC
	3950	ST-T abnormalities	ECG/ECO-Doppler	No structural cardiopathy	Discharge
	18121	Incomplete LBBB and possible septal preexcitation	ECG/ECO-Doppler	No structural cardiopathy	Discharge
2012	29125	Atrial premature beats with abnormal conduction	ECG/ECO-Doppler	APB with abnormal conduction	AC
	17427	Negative progression of QRS complexes	ECG/ECO-Doppler	MVP on postero-septal valve	2 years-control
	11707	QT interval abnormalities	ECG/ECO-Doppler	No structural cardiopathy	Discharge
2013	3047	Bifascicular block	ECG/ECO-Doppler	Bifascicular block	Holter 24h / AC
	12533	Multiple VPB + Sinus bradycardia	ECG/ECO-Doppler	Sinus bradycardia	Holter 24h / AC
	21619	Bifascicular block	ECG/ECO-Doppler	Bifascicular block	Holter 24h / AC
	12312	QT interval abnormalities	ECG/ECO-Doppler	No structural cardiopathy	Discharge
	25815	QRS voltage criteria for LVH and TWI	ECG/ECO-Doppler	RBBB, LVH and short PR	AC
	7482	Incomplete RBBB + Sinus bradycardia	ECG/ECO-Doppler	Sinus bradycardia	Holter 24h / AC
	31538	QRS voltage criteria for LVH and TWI	ECG/ECO-Doppler	No structural cardiopathy	Discharge
	8094	Multiple VPB	ECG/ECO-Doppler	No structural cardiopathy	Discharge

AC= Annual control / AR= aortic regurgitation / APB= atrial premature beat / AV= atrioventricular / ECG= electrocardiogram / EST= exercise stress test / LBBB=left bundle branch block / LVH=left ventricular hypertrophy / MRIc= cardiac magnetic resonances imaging / MVP= mitral valve prolapse / RBBB=right bundle branch block / SR= sinus rhythm / TWI= t waves inversion / VPB= ventricular premature beat

Table 5: Statistical analysis results

<u>Variables</u>	<u>OR</u>	<u>95% IC</u>	<u>p-value</u>
Family history	0,91	(0,49 - 1,69)	0,76
Palpitations	0,85	(0,57 - 1,28)	0,44
Loss of consciousness	0,99	(0,62 - 1,59)	0,97
Medication	0,9	(0,54 - 1,94)	0,67
Gender	1,55	(1,16 - 2,08)	<0,01

Figure 2: Statistical signification of OR



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13- ANNEXES

13.1- Annex 1

CONSENTIMENT INFORMAT

ESTUDI DE L'ELECTROCARDIOGRAMA EN ALUMNES DE 2º D'ESO AL PLA DE L'ESTANY

INFORMACIÓ GENERAL

Convidem al seu fill/filla a participar en un projecte d'exploració electrocardiogràfica en alumnes de 2n d'ESO. Abans de signar aquest consentiment, prengui el temps necessari per llegir i comprendre tota la informació. Pregunti al seu metge o a un membre del personal mèdic tots els dubtes que tingui sobre aquest estudi i sobre els seus drets. Ells estan preparats per contestar totes les seves preguntes.

Li demanem que llegiu aquest document perquè compregui aquest estudi i la manera en què el seu fill/filla pot participar. Signant aquest document vostè està consentint a la participació del seu fill/filla en aquest estudi.

PROPÒSIT DE L'ESTUDI

El propòsit de l'estudi és identificar en una població de joves de 2n d'ESO de la ciutat de Banyoles (entre 13 i 15 anys) alteracions electrocardiogràfiques causades per un grup de malalties cardíques que potencialment poden causar arítmies cardíques, pèrdues sobtades del coneixement i/o mort sobtada (com la síndrome de Wolf-Parkinson-White, la síndrome de Brugada, la síndrome de QT llarg, la síndrome de QT curt, la miocardiopatia hipertròfica i la displàsia aritmogènica de ventricle dret). Aquestes malalties solen alterar l'electrocardiograma basal, i la seva detecció primerenca redunda en la prevenció d'esdeveniments cardíacs malignes, mitjançant la implementació d'un tractament mèdic adequat. També li preguntarem al seu fill/filla si ha tingut algun símptoma relacionat amb aquestes malalties (com palpitations, pèrdua del coneixement, convulsions) i si hi ha antecedents familiars de les mateixes.

PROCEDIMENT

Recollida de dades clíniques i antecedents familiars

Abans de realitzar l'electrocardiograma, li demanarem al seu fill/filla respondre a un petit qüestionari, sobre l'existència de símptomes com pèrdues de coneixement, palpitations (sensació de batecs cardíacs forts i/o ràpids), convulsions en el passat, així com també antecedents familiars de mort sobtada en persones joves i presumptament sanes (mort brusca en algun familiar menor de 50 anys).

Realització de l'electrocardiograma de 12 derivacions

L'electrocardiograma és el registre no invasiu de l'activitat elèctrica del cor. Per realitzar-lo, l'individu ha d'estar recolzat en una llitera, i connectat a un electrocardiògraf mitjançant 10 elèctrodes (cables) a la pell: 1 elèctrode en cadascuna de les extremitats, i 6 elèctrodes sobre la pell del pit. A continuació es registra l'electrocardiograma (procediment que dura aproximadament 1 minut). Realitzar un electrocardiograma no produeix cap molèstia ni dolor. A continuació es desconnecten els elèctrodes, i el traçat de l'electrocardiograma ha de ser interpretat per un cardiòleg.

COMUNICACIÓ DE RESULTATS

Una vegada que l'electrocardiograma sigui informat per un cardiòleg, rebrà vostè un informe escrit amb el resultat.

Si l'electrocardiograma és anormal i/o els símptomes del seu fill/filla fan sospitar una malaltia cardíaca, serà derivat a un cardiòleg, per aprofundir l'avaluació del seu fill/filla.

RISCOS/MOLÈSTIES

No existeix risc físic, ni molèsties. Per realitzar un electrocardiograma només cal connectar uns elèctrodes (cables) als membres i al tòrax, estant recolzat, durant 1 minut.

BENEFICIS

La informació obtinguda durant la investigació pot resultar en el diagnòstic precoç d'una malaltia cardíaca en el seu fill i la seva família, amb la possibilitat de rebre de manera primerenca un tractament adequat. En cas de no tenir cap malaltia, tindrà la tranquil·litat que el seu fill/filla pot realitzar activitats físiques sense cap risc per a la seva salut. En tot cas, se li oferirà la possibilitat de conèixer els resultats.

PARTICIPACIÓ VOLUNTÀRIA

La participació és voluntària i pot rebutjar o aturar la participació del seu fill/filla en qualsevol moment amb només expressar-ho verbalment.

La seva decisió de deixar el seu fill/filla participar o no en l'estudi no influenciarà la qualitat de les cures mèdiques que el seu fill/filla té dret a rebre.

CONFIDENCIALITAT

Els electrocardiogrames i les enquestes realitzades al seu fill/filla seran codificats, per tal d'assegurar la protecció de la seva identitat. El personal involucrat en la investigació no podrà identificar personalment a ningú a partir de l'anàlisi de l'electrocardiograma o les enquestes. La informació mèdica que es trobarà en l'informe de recerca del seu fill/filla en una base de dades en un ordinador, no permetrà la seva identificació. Les informacions donades a tercers (és a dir el personal de recerca o col·laboradors en l'estudi) tampoc ho permetran. Qualsevol dada de l'informe del seu fill/filla que permeti la seva identificació (el seu nom, número de pacient, adreça...) serà eliminat i reemplaçat per un codi de manera que no se li pugui identificar. Les dades del seu fill/filla poden ser publicats, però ell o ella no serà identificat pel nom. Així les dades i mostres del seu fill/filla es mantindran confidencials en tot moment. El Dr. Brugada, com a investigador principal d'aquest estudi, es compromet a garantir el compliment dels principis establerts en la Llei Orgànica de caràcter personal 15/1999 i a facilitar els seus drets d'accés, rectificació, cancel·lació i oposició a les dades i/o electrocardiogrames. En cas que aquests fossin transferits a altres països, s'adoptaran les mesures necessàries per garantir la protecció de dades d'acord amb la legislació vigent a Espanya.

RETRIBUCIONS

El seu fill/filla no rebrà cap aportació econòmica per la seva participació en aquest estudi.

PROJECTE D'ESTUDI DE L'ELECTROCARDIOGRAMA EN ALUMNES DE
2º D'ESO A LA COMUNA DE BANYOLES

MENOR D'EDAT

Investigador:

Totes les meves preguntes sobre l'estudi s'han contestat satisfactòriament.

Comprenc que puc retirar al meu fill/filla de l'estudi en qualsevol moment sense afectar les cures mèdiques que pugui requerir en un futur.

Autoritzo a l'investigador a consultar l'informe mèdic del meu fill/filla i a guardar-lo dins d'un dossier d'investigació sense incloure dades que el/la identifiquin.

Autoritzo a l'investigador a transmetre les dades i electrocardiograma al meu fill/filla a personal implicat en l'estudi sense incloure dades que l'identifiquin.

He rebut una còpia d'aquest document i he tingut temps suficient abans d'accedir a que el meu fill/filla participin en aquest estudi.

Desitjo que m'informin dels resultats de l'estudi del meu fill/filla quan estiguin disponibles.

Si ____ No ____

_____ Firma del pare/mare

_____ Nom en lletra de impremta

_____ Data i Hora

_____ Nom del menor d'edat

_____ Firma de l'investigador

_____ Nombre en lletra de impremta

_____ Data i Hora

Dña. Begoña Gómez Pérez , del Servicio de Farmacia del Hospital
Clínic de Barcelona y Secretaria del Comité Ético de Investigación
Clínica (CEIC)

CERTIFICA:

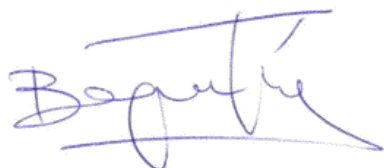
Que el Comité Ético de Investigación Clínica, según consta en el acta
de la reunión celebrada en el día de hoy, ha analizado el proyecto de
investigación titulado:

*Projecte d'estudi de l'electrocardiograma en alumnes de 2n d'ESO a la
comuna de Banyoles.*

cuyo investigador principal es el Dr. **Brugada, Josep**
del Servicio de **Cardiología**

entendiendo que dicho estudio se ajusta a las normas éticas esenciales
y criterios deontológicos que rigen en este Centro, y, por tanto, ha
decidido su aprobación.

Lo que firmo en Barcelona, a 15/04/2010



CLÍNICA
BARCELONA
Hospital Universitari
COMITÉ ÈTIC
INVESTIGACIÓ CLÍNICA

D. Joan Albert Barberá Mir, Adjunto a la Dirección de Investigación del Hospital Clínic de Barcelona,

CERTIFICA:

Que el Comité de Investigación del Hospital Clínic, en la sesión celebrada en el día de hoy, ha analizado el proyecto de investigación titulado:

Projecte d'estudi de l'electrocardiograma en alumnes de 2n d'ESO a la comuna de Banyoles.

cuyo investigador principal es el Dr. **Brugada, Josep** del Servicio de **Cardiología** entendiendo que dicho estudio se incluye en una de las líneas de investigación biomédica acreditadas en este centro, cumpliendo los requisitos metodológicos necesarios, y que es viable en todos sus términos, por lo que lo ha considerado adecuado y ha decidido su aprobación.

Lo que firmo en Barcelona, a 15/04/2010



CLÍNIC
BARCELONA
Hospital Universitari
COMITÉ ÈTIC
INVESTIGACIÓ CLÍNICA

Registro: 2010 / 5750

13.3- Annex 3

ENQUESTA SOBRE SÍMPTOMES I ANTECEDENTS FAMILIARS **PROJECTE D'ESTUDI DE L'ELECTROCARDIOGRAMA EN ALUMNES DE** **2n D'ESO A LA COMUNA DE BANYOLES**

Respon a les següents preguntes marcant una creu a la casella corresponent:

ANTECEDENTS FAMILIARS:

- 1) Algú en la teva família va morir de manera sobtada (bruscament, sense cap avís)?

☐ Si ☐ No

- 2) Quina relació tenies amb aquesta persona?

- ☐ Era el meu pare/mare
☐ Era el meu germà/germana
☐ Era el meu tiet/a
☐ Era el meu cosí/cosina
☐ Era mi avi/a
☐ Altres (explicar):

.....
.....

- 3) Quina edat tenia el teu familiar quan va morir sobtadament?.....anys.

ANTECEDENTS PERSONALS

- 1) Alguna vegada has sentit palpitations (sensació que el teu cor batega ràpid i/o fort)?

☐ Sí ☐ No

- 2) Alguna vegada has perdut el coneixement (desmaiar-te, caure al terra com adormit)?

☐ Sí ☐ No

- 3) Alguna vegada t'han dit que eres epilèptic o has tingut convulsions?

☐ Sí ☐ No

- 4) Prens algun tipus de medicació?

☐ Sí ☐ No

- 5) Nom del/s medicament/s que prens:

.....
.....

13.4- Annex 4

CRONOGRAMA DE TREBALL

PROGRAMACIÓ ESTUDI ECG ANY 2010

<u>Data</u>	<u>Hora</u>	<u>Centre educatiu</u>
Dimarts 04-05-2010	15:00-17:00	IES Pla de l'Estany
Dimecres 05-05-2010	15:00-17:00	Escola Casa Nostra
Dijous 06-05-2010	15:30-17:30	IES Pere Alsius i Torrent
Dilluns 10-05-2010	15:30-17:30	IES Josep Brugulat
Dimarts 11-05-2010	15:00-17:00	IES Pla de l'Estany
Dijous 13-05-2010	15:30-17:30	IES Pere Alsius i Torrent
Dilluns 17-05-2010	15:30-17:30	IES Josep Brugulat
Dimarts 18-05-2010	15:00-17:00	IES Pla de l'Estany
Dijous 20-05-2010	15:30-17:30	IES Pere Alsius i Torrent
Dilluns 24-05-2010	15:30-17:30	IES Josep Brugulat

PROGRAMACIÓ ESTUDI ECG ANY 2011

<u>Data</u>	<u>Hora</u>	<u>Centre educatiu</u>
Dilluns 21-03-2011	15:30-17:30	IES Josep Brugulat
Dimarts 22-03-2011	15:30-17:30	IES Josep Brugulat
Dimecres 23-03-2011	15:00-17:00	Escola Casa Nostra
Dijous 24-03-2011	15:30-17:30	IES Pere Alsius i Torrent
Dilluns 28-03-2011	15:30-17:30	IES Josep Brugulat
Dimarts 29-03-2011	15:00-17:00	IES Pla de l'Estany
Dijous 31-03-2011	15:30-17:30	IES Pere Alsius i Torrent
Dilluns 04-04-2011	15:00-17:00	IES Pla de l'Estany
Dimarts 05-04-2011	15:00-17:00	IES Pla de l'Estany
Dijous 07-04-2011	15:30-17:30	IES Pere Alsius i Torrent

PROGRAMACIÓ ESTUDI ECG ANY 2012

<u>Data</u>	<u>Hora</u>	<u>Centre educatiu</u>
Dilluns 07-05-2012	15:00-17:00	IES Josep Brugulat
Dimarts 08-05-2012	15:30-17:30	IES Josep Brugulat
Dimecres 09-05-2012	15:00-17:00	Escola Casa Nostra
Dilluns 14-05-2012	15:00-17:00	IES Pere Alsius i Torrent
Dimarts 15-05-2012	15:30-17:30	IES Pere Alsius i Torrent
Dijous 17-05-2012	9:00-13:00	IES Pla de l'Estany

PROGRAMACIÓ ESTUDI ECG ANY 2013

<u>Data</u>	<u>Hora</u>	<u>Centre educatiu</u>
Dilluns 15-04-2013	13:00-15:00	IES Josep Brugulat
Dimarts 16-04-13	13:00-15:00	IES Josep Brugulat
Dimecres 17-04-13	9:30-13:50	IES Pere Alsius i Torrent
Dimecres 17-04-13	15:00-18:00	Escola Casa Nostra
Dijous 18-04-13	9:00-13:00	IES Pla de l'Estany